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Sentinel lymph node biopsy for melanoma of the head and neck: a multicentre study to examine safety, efficacy, and prognostic value

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Abstract

Sentinel lymph node biopsy (SLNB) is an accurate staging procedure for malignant melanoma but its use in patients with melanoma of the head and neck has been questioned in the past because of a perceived record of poor safety and accuracy. Technical improvements have sought to redress this. Vital structures and variable lymphatic pathways can make its use in the head and neck challenging. In our study we have examined the data and the experiences of clinicians from University Hospital Southampton and the Royal Surrey County Hospital. We retrospectively analysed the data and case notes of 143 patients who had SLNB to establish its safety, efficacy, and prognostic value. The detection rate of at least one sentinel lymph node was 100%. Nodes positive for metastatic melanoma were found in 20% of patients. Of them, 76% went on to have completion lymphadenectomy. Multivariate Cox regression analysis suggested that positive SLNB was a strong predictor of reduced overall survival for all Breslow-thickness melanomas (HR = 3.9, p = 0.019) and intermediate melanomas (HR = 6.3, p = 0.007). It predicted reduced recurrence-free survival for all melanomas (HR = 7.4, p < 0.001) and was a strong predictor for those of intermediate thickness (HR = 8.3, p < 0.001). The false negative rate was 9.4% and false omission rate 2.6%. Temporary and permanent morbidity rates were 2.1% and 0%, respectively. SLNB for melanoma in the head and neck is a safe, accurate staging procedure that offers prognostically useful information. The upstaging of disease allows access to trial-based targeted treatments.

Keywords: melanoma; sentinel lymph node biopsy; safety; efficacy; prognostic value; head and neck melanoma

Introduction

In the UK in 2015 there were 15 900 new cases of melanoma.[1] About 22% of new cases occur in the head and neck[2] and the incidence has more than quadrupled since the late 1970s.[3] In the absence of any metastases, the region is consistently associated with a poorer prognosis than others for all categories of tumour thickness.[4] Sentinel lymph node biopsy (SLNB) was first described by Morton et al in 1992,[5] and

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is now well accepted as a staging technique for malignant melanoma.[6] Through detailed analysis of the sentinel node (which is defined as the first node to receive tumour deposits[5]) it aims to establish the metastatic status of the nodal basin that drains the primary tumour.

For melanomas of the head and neck,[7] and also for those of other sites,[8] the status of the sentinel node has been reported to be more predictive of both overall and recurrence-free survival than well-established measures such as Breslow depth, mitotic rate, ulceration, and age of the patient. Lymphatic drainage of the head and neck is more unpredictable (based on previously accepted drainage patterns),[9] and varies more than in other regions.[10] In a systematic review, de Rosa et al estimated the false negative rate for SLNB in melanoma of the head and neck to be 20.4%.[11] This compares unfavourably with figures for melanoma of the trunk and limb, which often range from 3% to 5%.[12,13] In addition to the variable lymphatic drainage, the close proximity to critical structures in the head and neck results in increased morbidity, although more recent work has suggested that this can be managed safely.[7,14]

SLNB can identify patients with clinically occult nodal metastases, potentially enabling them to have immediate completion lymph node dissection, adjuvant drug treatment, or to take part in clinical trials. Recently published results of the MSLT-2 trial have suggested that immediate completion lymph node dissection after a positive SLNB reduces the risk of recurrence more than ultrasound surveillance of the nodal basin, but does not improve melanoma-specific survival.[15] In this multicentre observational study therefore, we have sought to establish the accuracy, safety, and prognostic value of SLNB in the head and neck.

Methods

Ethics approval was granted (ERGO 19042) by the Ethics Committee of the Faculty of Medicine, University of Southampton, for data collection from the University Hospital Southampton and the Royal Surrey County Hospital.

The data on patients who had SLNB between May 2011 and September 2017 were collected retrospectively from case notes by the authors (BPW, BG, JL, JS, and MP) until October 2018. All patients were followed up for at least one year or until an event of interest. They were also evaluated at the weekly melanoma clinics of authors SS and CN. Histological samples were analysed by histopathologists from both hospitals. Patients with tumours with a Breslow depth of more than 1 mm; or a Breslow depth of less than 1 mm, but a mitotic rate of more than 1; or the presence of ulceration, were considered for SLNB according to the American Joint Committee on Cancer (AJCC) melanoma staging system. Those who had a positive SLNB result had staging CT after which completion lymph node dissection was discussed and offered. Trial-based treatments were also offered if appropriate. Patients with a negative result had routine clinical review according to National Institute of Health and Care Excellence (NICE) guidelines.

All patients who were offered SLNB had preoperative lymphoscintigraphy to identify the sentinel node. This was done either the day before, or four hours before SLNB. Technetium 99m-labelled sulphur colloid was injected intradermally around the site of the scar from the primary biopsy. Standard 2-dimensional planar dynamic images were acquired and single photon emission CT (SPECT) organised if required. As a guide, the site of the sentinel node was marked on the surface of the skin with a cobalt pen.

A combination of intraoperative gamma probe counts and Patent Blue dye were used to identify the sentinel lymph node. According to standard protocols all primary echelon nodes in the region were removed until the background count was less than 10% of the target count. Further wide excision with reconstruction of the primary site was done as appropriate. The lymph nodes that had been removed were fixed in 10% formalin, bisected, and serially sliced. For histopathological analysis they were then stained with haematoxylin and eosin and immunohistochemical stains to target the melanoma-specific antigens S100 and melan-A.

Primary endpoints were overall and recurrence-free survival. The time to endpoint analysis was calculated from the date of the SLNB. For overall survival, patients who had not died during the study period were censored at their last follow up. Recurrence was defined as local (metastases within 2 cm of the primary scar), regional (metastases in the nodal basin that drained the primary lesion as shown on lymphscintigraphy), or distant. When calculating recurrence-free survival, patients without recurrence or who were still alive were censored at the last follow up. A false negative was defined as a regional recurrence after negative SLNB, in the absence of local and distant recurrence.

Statistical analyses were done with the help of IBM SPSS Statistics for Windows version 25 (IBM Corp). Patients' details were summarised using descriptive statistics. All continuous variables were skewed. The Mann-Whitney U test was used to assess the difference in each continuous factor between positive and negative SLNB. Chi squared or Fisher's exact tests were used (where appropriate) to assess the association between categorical factors and SLNB status. Kaplan-Meier survival plots with log-rank tests were used to assess the differences in overall and recurrence-free survival between patients with a positive and negative SLNB.

Univariate and multivariate Cox proportional hazards regression analyses were done to identify significant prognostic factors in overall and recurrence-free survival. Factors that were thought to be relevant prognostic determinants of both were age at SLNB, result of SLNB, and features of the primary lesion such as the presence of ulceration, Breslow thickness, and mitotic rate. Separate final multivariate regression models for overall and recurrence-free survival

were produced using the backward elimination strategy. Non-significant predictors were removed iteratively until all the remaining covariates were significant ($p < 0.05$). A subgroup analysis of intermediate-thickness melanoma was also done, and the proportional hazards assumption for these models checked.

Results

Patients' characteristics

Data were collected on 181 patients. A total of 38 were excluded (27 who were followed up for less than one year, and 11 who had failed lymphoscintigraphy and had therefore not had SLNB), which left 143 patients in the study. The median (range) age at SLNB was 66 (8–93) years, and the median follow up time was over 33 months. The two commonest melanoma sites were the preauricular region of the cheek (24%), and forehead/temple/eyebrow (20.7%); the two least common were the parietal and postauricular regions (4.1%), and nose (3.3%). The median (range) Breslow depth was 1.8 (0.4–15) mm, median (range) mitotic rate was 3 (0 - 40) mitoses/mm,[2] and ulceration was present in 22.8% of melanomas. Table 1 gives a more detailed breakdown of the patients' characteristics.

Lymphoscintigraphy

Of the 102 patients for whom there were data regarding lateralisation of the drainage (as seen on lymphoscintigraphy) in relation to the primary site, 95 (93.1%) were unilateral, 4 (3.9%) bilateral, and 3 (2.9%) contralateral.

Sentinel lymph node biopsy (SLNB)

At least one sentinel node was found in all the patients who had SLNB ($n = 143$). The median (range) number of sentinel nodes harvested was 1 (1–6) (Table 1). A total of 29 patients (20.3%) had metastatic disease (positive SLNB). The tumours in patients with positive SLNB were significantly thicker (Breslow) than those in whom it was negative ($p < 0.001$).

Completion lymph node dissection

Of the 29 patients with a positive SLNB, 22 subsequently had completion lymph node dissection (six did not and one was unknown). All cases of positive SLNB were discussed at multidisciplinary meetings and a decision for ultrasound surveillance alone was made in two cases in which the tumour burden was low. Of the three patients who had an unexpected regional recurrence after a negative SLNB, only one had completion lymph node dissection. When this was done after a positive SLNB, it yielded further invaded nodes in 6/22 operations, and was negative for metastatic disease in 16/22 patients. Of the 16 patients who had no sign of disease on completion lymph node dissection, 11 went on to develop recurrences.

Recurrence of disease and false omission rate

Of the 29 patients with a positive SLNB, 18 had recurrence (local in four, regional in 10, and distant in four). Of all 114 patients who had a negative SLNB, 10 (8.8%) had recurrence (local in three, regional in three, and distant in four). After negative SLNB, three had regional recurrences (all without local recurrence), which gave a false omission rate of 2.6% ($3/(3 + 111)$). SLNB therefore had a negative predictive value for regional recurrence of 97.4%, and a false negative rate of 9.4% ($3/(3 + 29)$).

Survival analysis

Twelve patients died (six with a positive SLNB result and six with a negative result). Mean overall survival was significantly shorter in the positive SLNB group (63.1 months, 95% CI 53.0 to 73.1) than in the negative group (84.1 months, 95% CI 79.7 to 88.5) ($p = 0.011$). Analysis of recurrence-free survival showed that there were 19 recurrences or deaths in the positive group and 13 in the negative group. Mean recurrence-free survival was significantly shorter in the positive group (32.7 months, 95% CI 20.9 to 44.5) than in the negative group (78.4 months, 95% CI 72.7 to 84.1) ($p < 0.001$) (Fig. 1). Subgroup analysis of intermediate-thickness melanomas is shown in Fig. 2.

Univariate, full, and final Cox regression models are shown in Tables 2A2D. The final model suggested that, regardless of thickness, a positive SLNB was the most significant predictor of reduced overall survival (hazard ratio (HR) = 3.91; 95% CI 1.25 to 12.18; $p = 0.019$), and was also a significant predictor of recurrence-free survival (HR = 7.40; 95% CI 3.61 to 15.14; $p < 0.001$), together with the Breslow depth of the primary tumour ($p = 0.005$). For intermediate-thickness melanomas, a positive SLNB was the strongest predictor of a reduction in both overall (HR = 6.28; 95% CI 1.67 to 23.66; $p = 0.007$) and recurrence-free survival (HR = 8.25; 95% CI 3.16 to 21.51; $p < 0.001$) after adjusting for ulceration of the primary, though with a very wide confidence interval.

Safety

Temporary complications occurred in only three patients (one in each): weakness of the marginal mandibular branch of the facial nerve, chyle leak, and paraesthesia in the right cheek. This gave a temporary morbidity rate of 2.1%. There were no permanent complications.

Table 1
Patients' details. Data are number (%) unless otherwise stated.

Patient demographics	Overall	SLNB result		p value
		Negative	Positive	
No. of patients	143	114	29	
Age (years):				
Median (IQR)	66.5 (50.4–74.7)	68.3 (55.5–75.0)	49.6 (36.8–70.2)	0.003[1]
Range	8.4–92.6	18.6–92.6	8.4–88.3	
Follow-up time (months):				
Median (IQR)	33.4 (19.7–52.7)	33.0 (19.7–51.9)	36.3 (16.5–62.8)	0.966[1]
Range	7.3–89.5	8.3–89.5	7.3–77.3	
No. of nodes collected at SLNB:				
Median (IQR)	1 (1–2)	1 (1–2)	1 (1–2)	0.872[1]
Range	1–6	1–6	1–5	
Not recorded	28	25	3	
Primary site:				
Scalp	11 (9)	3 (3)	8 (31)	0.001[2]
Parietal/postauricular	5 (4)	4 (4)	1 (4)	
Forehead/temple/eyebrow	25 (21)	21 (22)	4 (15)	
Eye	10 (8)	8 (8)	2 (8)	
Ear	17 (14)	17 (18)	0	
Nose	4 (3)	2 (2)	2 (8)	
Lip/chin/jawline/submentum	7 (6)	7 (7)	0	
Preauricular/cheek	29 (24)	24 (25)	5 (19)	
Neck	13 (11)	9 (10)	4 (15)	
Not recorded	22	19	3	
Breslow depth (mm):				
Median IQR)	1.8 (1.0–3.4)	1.5 (1.1–2.6)	3.1 (1.9–4.7)	<0.001[1]
Range	0.4–15.0	0.4–15.0	0.8–9.5	
Not recorded	6	5	1	
Thickness (mm):				
Thin <1	12 (9)	11 (10)	1 (4)	0.005[2]
Intermediate ≥1–≤4	104 (76)	87 (80)	17 (61)	
Thick >4	21 (15)	11 (10)	10 (36)	
Not recorded	6	5	1	
Mitotic rate (mitoses/mm):				
Median (IQR)	3.0 (1.0–8.0)	2.0 (1.0– 7.0)	6.5 (2.0–10.0)	0.038[1]
Range	0–40.0	0–40.0	0.5–28.0	
Not recorded	20	17	3	
Ulceration:				
Present	28 (23)	19 (20)	9 (33)	0.138[3]
Absent	95 (77)	77 (80)	18 (67)	
Not recorded	20	18	2	

SLNB: sentinel lymph node biopsy.
[1] Mann–Whitney U test.
[2] Fisher's exact test.
[3] Chi squared test.

Discussion

Our study provides further evidence for the safety and efficacy of SLNB in patients with melanoma of the head and neck. Our results are similar to those in other recently published reports that show that SLNB can be done with a high degree of accuracy in specialist centres.[16–18]

Accuracy

Previous research has highlighted the relative unpredictability of lymphatic drainage in the head and neck.[10] Our detection rate at operation was 100%, which is comparable to those reported in the MSLT-1 trial (97.5% for melanomas not in the head and neck)[19] and the Sunbelt trial[20] (99.7% for all sites).–

The positivity rate for SLNB in our study was 20.3%, which is comparable with that reported in the MSLT-1 trial (20.8% for all melanoma sites). In this trial the median Breslow thickness in the biopsy arm was also similar to that in our study (1.8 mm). The positivity rate in our study was also comparable with those reported in other studies (17.6%,[16] and 19.7%[7]) that focused only on the head and neck.

We found a false negative rate of 9.4%, which was comparable with rates reported in other studies (14.8%,[7] and 9.5%[14]). The false omission rate of 2.6% indicated the greater accuracy of the procedure in the identification of negative

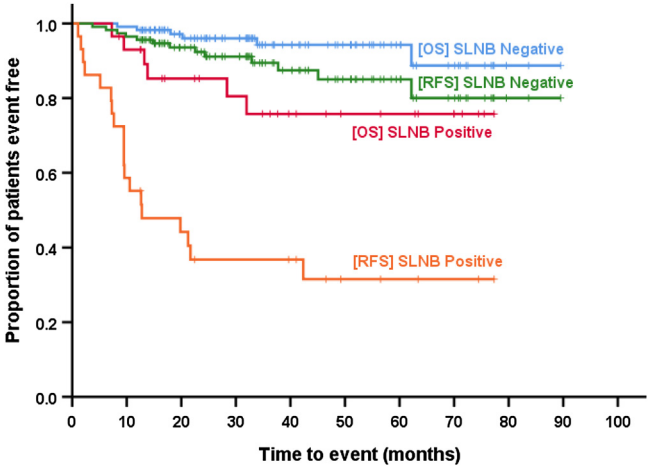

Fig. 1. Kaplan–Meier survival curve for overall survival (OS) and recurrence-free survival (RFS) in all patients by SLNB status: OS SLNB positive: number of events = 6, mean (95% CI) time to death = 63.1 (53.0 to 73.1); OS SLNB negative: number of events = 6, mean (95% CI) time to death = 84.1 (79.7 to 88.5) (log-rank test p = 0.011); RFS SLNB positive: number of events = 19, mean (95% CI) time to recurrence = 32.7 (20.9 to 44.5); RFS SLNB negative: number of events = 13, mean (95% CI) time to recurrence = 78.4 (72.7 to 84.1) (log-rank test p < 0.001). The vertical markers on the survival curves are censored observations.

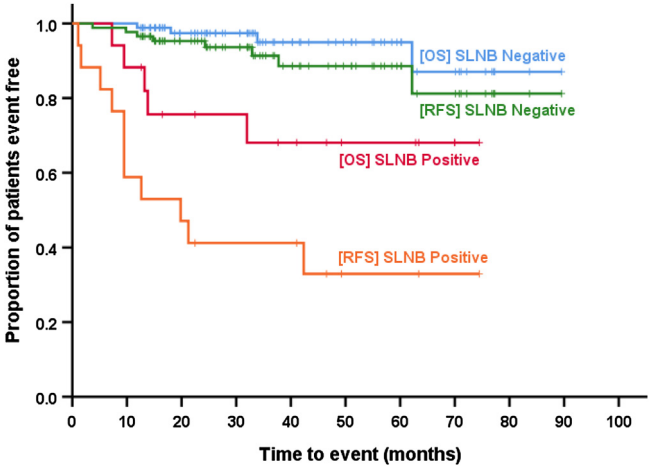

Fig. 2. Kaplan–Meier survival curve for reduced overall survival (OS) and recurrence-free survival (RFS) in patients with intermediate-thickness melanoma by SLNB status: OS SLNB positive: number of events = 5, mean (95% CI) time to death = 55.8 (42.1 to 69.5); OS SLNB negative: number of events = 4, mean (95% CI) time to death = 84.1 (78.7 to 89.5) (log-rank test p = 0.002); RFS SLNB positive: number of events = 11, mean (95% CI) time to recurrence = 33.7 (19.1 to 48.3); RFS SLNB negative: number of events = 8, mean (95% CI) time to recurrence = 80.0 (73.5 to 86.4) (log-rank test p < 0.001). The vertical markers on the survival curves are censored observations.

cases. Reported studies have predicted a lower false omission rate for melanomas in sites other than the head and neck (MSLT-1: 3.4%,[13] and the European Organisation for Research and Treatment of Cancer (EORTC) Melanoma Group: 4.7%[12]), but a higher rate of 9.3% for those in the head and neck, as shown in a group of eight datasets compiled by Erman et al.[7] Our own dataset showed a lower rate than those reported for melanomas of the head and neck.

Prognostic value

The low false omission rate and high negative predictive value of 97.4% show that SLNB has a high prognostic value, but does not take into account distant and local recurrence, which made up seven of our 10 instances of recurrence in patients whose SLNB was negative.

Mean recurrence-free survival was significantly lower in the positive SLNB group than it was in the negative group. On multivariate analysis of all melanomas for reduced recurrence-free survival, positive SLNB was the strongest predictor (HR = 7.40, p < 0.001), and was also a strong predictor for those of intermediate thickness only (HR = 8.25, p < 0.001) after adjusting for ulceration of the primary (though with a wide 95% CI). The hazard ratio for all melanomas was higher than that proposed in larger studies by Leong et al[21] (HR = 2.8) and Erman et al (HR = 4.2),[7] but comparable with reports in smaller studies such as that by Hafström et al (HR = 5.7).[18]

Mean overall survival was significantly lower in the positive SLNB group than in the negative group, and multivariate analysis showed that for all melanomas, a positive SLNB was a significant predictor of reduced overall survival (HR = 3.91,

Table 2A
Univariate and multivariable Cox proportional hazards models predicting overall survival in patients with melanoma of the head and neck (all thicknesses) who had sentinel lymph node biopsy (SLNB).

Overall survival in all patients	Univariate model (Maximum n = 143)				Full model (n = 115)			Final model (n = 143)		
	No.	HR	(95% CI)	p value	HR	(95% CI)	p value	HR	(95% CI)	p value
SLNB result:										
Negative	114	1			1			1		
Positive	29	3.91	(1.25, 12.18)	0.019	4.67	(1.28, 17.11)	0.020	3.91	(1.25, 12.18)	0.019
Ulceration of primary:										
Negative	95	1			1			–		
Positive	28	1.28	(0.34, 4.76)	0.715	1.11	(0.25, 4.99)	0.889	–	–	–
Age at SLNB (years)	143	1.01	(0.97, 1.04)	0.784	1.02	(0.99, 1.06)	0.225	–	–	–
Breslow depth of primary (mm)	137	1.12	(0.92, 1.36)	0.254	1.00	(0.76, 1.31)	0.989	–	–	–
Mitotic rate of primary (mitoses/mm^2)	123	1.03	(0.97, 1.09)	0.295	1.03	(0.96, 1.10)	0.452	–	–	–

Table 2B
Univariate and multivariable Cox proportional hazards models predicting overall recurrence-free survival in patients with melanoma of the head and neck (all thicknesses) who had sentinel lymph node biopsy (SLNB).

Recurrence-free survival in all patients	Univariate model (Maximum n = 143)				Full model (n = 115)			Final model (n = 137)		
	No.	HR	(95% CI)	p value	HR	(95% CI)	p value	HR	(95% CI)	p value
SLNB result:										
Negative	114	1			1			1		
Positive	29	8.38	(4.12, 17.03)	<0.001	6.26	(2.57, 15.25)	<0.001	7.40	(3.61, 15.14)	<0.001
Ulceration status of primary:										
Negative	95	1			1			–		
Positive	28	2.85	(1.36, 5.98)	0.005	1.50	(0.58, 3.91)	0.403	–	–	–
Age at SLNB (years)	143	0.99	(0.97, 1.01)	0.162	1.00	(0.98, 1.03)	0.699	–	–	–
Breslow depth of primary (mm)	137	1.22	(1.10, 1.34)	<0.001	1.19	(1.01, 1.42)	0.042	1.19	(1.05, 1.34)	0.005
Mitotic rate of primary (mitoses/mm^2)	123	1.04	(1.01, 1.08)	0.021	1.03	(0.98, 1.08)	0.309	–	–	–

Table 2C
Univariate and multivariable Cox proportional hazards models predicting overall survival in patients with intermediate-thickness melanoma of the head and neck who had sentinel lymph node biopsy (SLNB).

Overall survival in patients with intermediate-thickness melanoma	Univariate model (Maximum n = 104)				Full model (n = 86)			Final model (n = 104)		
	No.	HR	(95% CI)	p value	HR	(95% CI)	p value	HR	(95% CI)	p value
SLNB result:										
Negative	87	1			1			1		
Positive	17	6.28	(1.67, 23.66)	0.007	7.22	(1.58, 32.99)	0.011	6.28	(1.67, 23.66)	0.007
Ulceration of primary:										
Negative	74	1			1			–		
Positive	16	3.38	(0.80, 14.25)	0.098	2.58	(0.48, 13.86)	0.269	–	–	–
Age at SLNB (years)	104	1.00	(0.96, 1.04)	0.972	1.02	(0.98, 1.06)	0.408	–	–	–
Breslow depth of primary (mm)	104	2.13	(1.12, 4.05)	0.022	1.53	(0.76, 3.10)	0.238	–	–	–
Mitotic rate of primary (mitoses/mm^2)	91	1.05	(0.98, 1.12)	0.137	1.04	(0.96, 1.12)	0.367	–	–	–

Table 2D
Univariate and multivariable Cox proportional hazards models predicting recurrence-free survival in patients with intermediate-thickness melanoma of the head and neck who had sentinel lymph node biopsy (SLNB).

Recurrence-free survival in patients with intermediate thickness melanoma	Univariate model (Maximum n = 104)				Full model (n = 86)			Final model (n = 90)		
	No.	HR	(95% CI)	p value	HR	(95% CI)	p value	HR	(95% CI)	p value
SLNB result:										
Negative	87	1			1			1		
Positive	17	9.27	(3.71, 23.12)	<0.001	9.01	(2.86, 28.39)	<0.001	8.25	(3.16, 21.51)	<0.001
Ulceration of primary:										
Negative	74	1			1			–		
Positive	16	4.70	(1.71, 12.93)	0.003	2.42	(0.69, 8.46)	0.166	4.25	(1.49, 12.11)	0.007
Age at SLNB (years)	104	0.99	(0.96, 1.01)	0.398	1.00	(0.98, 1.03)	0.810	–	–	–
Breslow depth of primary (mm)	104	1.71	(1.08, 2.71)	0.022	1.36	(0.75, 2.46)	0.307	–	–	–
Mitotic rate of primary (mitoses/mm^2)	91	1.06	(1.01, 1.11)	0.026	1.05	(0.99, 1.12)	0.109	–	–	–

p = 0.019). This has also been shown in other studies,[7,16] but data remain conflicting.[21,22] In our subgroup analysis of intermediate-thickness melanomas, a positive SLNB was also a significant predictor of reduced overall survival (HR = 6.28, p = 0.007). The low rate of metastases in thin melanomas and high rate of distant metastases in thicker lesions could suggest that intervention in the intermediate group would make a difference to outcome.[8,23]

The main limitations of our study were the low number of events recorded (deaths and recurrences), and the relatively short follow-up time, which resulted in wide confidence intervals in some predictors.

The results of the MSLT-2 study have suggested that in cases of recurrence, immediate completion lymph node dissection has no melanoma-specific survival benefit when compared with ultrasound surveillance and delayed completion dissection. In light of this new evidence,[15] our protocols

now reflect these findings, and we use SLNB for stratification of risk and as a staging tool. According to our current guidelines, most patients are placed on a high-surveillance protocol, and considered for trial-based treatments. A small number are still offered completion lymph node dissection for local control when this is deemed appropriate by the multidisciplinary team.

Safety

Erman et al (n = 353)[7] and Hafström et al (n = 160)[18] reported no incidences of permanent morbidity. Our study, which mirrors these findings, suggests that previous emphasis on the morbidity of SLNB in the head and neck has been overstated.

In conclusion, we have shown SLNB to be a strong predictor of overall and recurrence-free survival, with a particularly strong prognostic value in melanomas of intermediate thickness. It is safe and accurate, and allows patients to be appropriately staged and stratified for risk, and therefore should continue to be the standard of care for patients with melanoma of the head and neck.

Conflict of interest

We have no conflicts of interest.

Ethics statement/confirmation of patients' permission

Ethics approval was granted by the institution's ethics committee. There is no identifying information in this submission.

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