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Regional nodal metastasis and 5-year survival in patients with thin melanoma in Queensland: a population-based study

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Abstract

Background: Optimal management of regional lymph nodes for thin cutaneous melanoma is uncertain. We evaluated regional lymph node involvement and 5-year melanoma-specific survival (MSS) in patients with thin (≤1 mm) primary melanoma.

Methods: Patients with a melanoma, American Joint Committee on Cancer Staging 8th Edition pT1a (<0.8 mm) or pT1b (ulceration; and/or 0.8–1.0 mm), diagnosed during 2001–2015 were identified from the Queensland Oncology Repository. We extracted demographic, pathology and clinical details, including sentinel lymph node biopsy (SLNB), regional nodal dissection and nodal recurrence. Poisson regression was used to assess recurrence risk in patients who did not undergo SLNB. The 5-year MSS was calculated using the Kaplan–Maier method with Cox regression to compare survival outcomes according to SLNB performance.

Results: Of the 27 824 eligible patients, 240 (0.9%) underwent SLNB. One hundred and seventy-eight patients (0.6%) without SLNB had nodal recurrence. Of the 4848 patients with a pT1b lesion, 166 (3.4%) had SLNB with 12 (7.2%) positive; of the remainder, 99 (2.1%) had clinical recurrence. Risk of recurrence was higher in males, nodular subtype and T1b lesions and lower if patients were aged >60 years. The 5-year MSS was similar for observed and SLNB cohorts (99.66% versus 98.92%) but worse for T1b lesions (98.90%) and clinical nodal recurrence (66.89%).

Conclusion: Overall prognosis for T1 melanoma is excellent with nodal involvement being rare. However, the American Joint Committee on Cancer 8th Edition T1b melanoma correlates with significantly worse 5-year MSS and increased regional nodal recurrence (notably for 0.8–1.0 mm lesions with ulceration). Further characterization of high-risk groups for nodal positivity that impacts patient outcome is needed for the pT1 melanoma cohort.

Introduction

Cutaneous melanoma is the most common cause of skin cancer mortality.[1] Within Queensland between 2010 and 2014, the annual age-standardized melanoma incidence was 72 per 100 000.[2] The majority of new melanoma diagnoses involve a thin primary lesion ≤1 mm, with the 20-year survival in this group approaching 96%.[3] The total number of patients dying from the disease annually is greater for thin lesions compared with thick melanomas (>4 mm), because of the volume of disease.[4] The regional lymph node basin is the most common site for metastasis.[5] For patients with a T1 melanoma, the optimal management of the regional nodes is unclear. Evidence supports thickness of 0.75–1.0 mm to be a key 'high-risk feature' in thin melanoma.[1,6,7] Analysis of a large cohort of patients has led the American Joint Committee on Cancer (AJCC) to reclassify T1 melanoma in its 8th Edition Staging

Manual into T1a (<0.8 mm) and T1b (0.8–1.0 mm; any ulceration ≤1 mm) recognizing the higher mortality risk of T1b lesions.[8]

The Multi-Centre Selective Lymphadenectomy Trial (MSLT-I) compared the outcomes of patients who underwent a wide excision of the primary melanoma alone with wide excision and sentinel lymph node biopsy (SLNB) in patients with high-risk primary melanoma.[9] SLNB provided more accurate staging and prognostic information for patients with melanoma >1.2 mm.[9] For T1 melanoma, the role for SLNB was less clear. Patients with thickness <1.2 mm were enrolled in the trial if they had high-risk features such as Clark level IV/V, Breslow thickness >0.75 mm and/or any ulceration. The relevance of SLNB in this subset was not analysed.

Morbidity rates ranging from 4.6%[10] to 10.1%[9] have been reported from SLNB; however, the complications tend to be low grade, relating to wound infection and seroma formation, which provides an impetus for utilizing the procedure for thin melanoma staging. The current Australian guidelines recommend SLNB be considered for patients with a melanoma >1 mm and also for patients with melanoma >0.75 mm with other 'high-risk pathological features'.[11] Although the presence of a positive sentinel node reflects a worse melanoma-specific survival (MSS), a Cochrane review in 2015 concluded there was insufficient evidence to support a therapeutic benefit from SLNB compared with nodal observation alone.[12] Given the lack of evidence for a survival benefit directly related to performing an SLNB, the uncertainty for the role of the procedure for this pT1 group seems reasonable. The nodal recurrence has been reported to be as low as 2.9% when patients with a T1 melanoma have been observed.[13] However, patients who develop clinical regional nodal recurrence have a higher risk of melanoma death than those with micro-metastasis discovered by SLNB.[14]

Using population data over a 15-year period, we wished to assess the outcomes of AJCC 8th Edition stage T1 melanoma patients related to their regional nodal management at the time of the definitive treatment of the primary melanoma. Specifically, our aims were to assess the nodal involvement following SLNB (when performed) and the regional nodal recurrence rate for patients who did not have an SLNB, with an assessment of the risk factors for nodal recurrence in this group. Also, we aimed to define the 5-year MSS related to regional nodal management.

Methods

Data for all patients diagnosed with a primary invasive cutaneous melanoma ≤1 mm (AJCC T1) from 1 January 2001 to 31 December 2015 were obtained from the Queensland Oncology Repository. These data are based on histology reports from the Queensland Cancer Register and Queensland Hospital Admitted Patient Data Collection, matched to the patient's management across all hospitals in Queensland. The data for this study included information on patient demographics, pathology reports, in-hospital treatment (including surgical procedures based on coded data and pathology reports) and outcomes, with deaths obtained from linkage to the statewide and national death registers. Patients were excluded if they had a further primary melanoma or initially presented with clinically involved nodes (Fig. S1). T-stage was classified according to the AJCC 8th Edition Staging, with 0.75–0.79 mm classified as 0.8 mm and 1.01–1.04 mm classified as 1 mm, to allow subclassification into T1a and T1b. Records of all patients who underwent regional nodal surgery were reviewed to ensure this was relevant to the site of the primary melanoma included in the study. SLNB was recorded as having been performed, its location and positivity status based on hospital admissions and/or pathology reports.

In patients who did not have an SLNB, regional recurrence was recorded if the patient underwent regional nodal surgery more than 100 days after the date of their definitive primary melanoma surgery, and histopathology from the nodal dissection reported lymph nodes positive for melanoma. This time threshold was used to differentiate genuine nodal recurrence from the small number of cases who presented initially with clinical nodal involvement and underwent more immediate resection. Time to regional nodal recurrence was calculated from the date of primary melanoma diagnosis. Sites of nodal recurrence were individually checked to ensure they related to the lymphatic drainage pattern of the primary melanoma reported. To ensure a minimum of 5 years follow-up, analyses of 5-year MSS were performed for patients diagnosed during 2001–2010. Time to death was measured from the time of diagnosis of the primary melanoma.

Ethical approval for this research was granted through Metro South Human Research Ethics Committee (Reference number HREC/16/QPAH/708).

Statistical analysis

Poisson regression was used to identify demographic and clinicopathological features on multivariate analysis associated with lymph node recurrence in patients who did not undergo SLNB, assessed by adjusted incidence rate ratios (IRRs) and 95% confidence intervals (CIs) using T-stage in place of thickness and ulceration, given the interdependence of these variables. The number of patients who underwent SLNB was too small to allow assessment of the clinical risk factors that may have influenced a positive result. The 5-year MSS was calculated using the Kaplan–Maier method. Cox regression was used for univariate analysis to compare MSS between groups and derive hazard ratios (HRs), 95% CI and *P*-values.

Results

Following exclusion of ineligible patients, from 2001 to 2015, there were 27 824 patients with a pT1 melanoma (Fig. S1). SLNB was performed in 240 patients (0.9%; less often in patients aged >60 years and when the melanoma was on the head and neck; Table S1). There were 4848 patients (17%) with a pT1b lesion with SLNB performed in 166 (3.4%) in this group across the 15 years, peaking at 36 SLNB (36/394 T1b cases, 9.1%) in 2014. The overall SLNB was positive in 14 patients (5.8%) with the rate increasing to 7.2% (12/166) for patients with a T1b lesion and to 17.6% (3/17) when the thickness was between 0.8 and 1.0 mm with ulceration (Table 1).

Table 1 Presence of regional nodal melanoma positivity at SLNB or following observation (without SLNB) according to pathology in patients with AJCC 8th Edition pT1 melanoma diagnosed from January 2001 to December 2015 in Queensland

	No SLNB *n* = 27 584	No SLNB – recurrence† *n* = 178	SLNB *n* = 240	SLNB – positive *n* = 14
Thickness (mm)				
0–<0.8	23 268	82 (0.4%)	82	2 (2.4%)
0.80–1.0	4316	96 (2.2%)	158	12 (7.6%)
Ulceration				
Present	643	14 (2.2%)	25	3 (12.0%)
Absent‡	26 941	164 (0.6%)	215	11 (5.1%)
T-stage§				
T1a	22 902	79 (0.3%)	74	2 (2.7%)
T1b total	4682	99 (2.1%)	166	12 (7.2%)
T1b ≥0.8 mm, ulc–	4039	85 (2.1%)	141	9 (6.4%)
T1b <0.8 mm, ulc+	366	3 (0.8%)	8	0 (0%)
T1b ≥0.8 mm, ulc+	277	11 (4.0%)	17	3 (17.6%)

†Median follow-up time = 9.6 years. ‡Unless stated as being present, ulceration was presumed to be absent. §T-stage as per the AJCC 8th Edition. AJCC, American Joint Committee on Cancer; SLNB, sentinel lymph node biopsy; ulc, ulceration.

For patients who did not have an SLNB, the median follow-up was 9.6 years (range 0–15 years). Nodal recurrence occurred in 178 (0.6%) patients, but was higher if T1b (2.1%) with the highest risk in patients with thickness 0.8–1.0 mm and ulceration (4%) (Table 1). The median time to regional recurrence was 2.1 years (range 0.3–9.8 years). The adjusted risk of regional recurrence is shown in Table 2. This was increased in males (adjusted IRR 1.65; 95% CI 1.20–2.28), nodular subtype (adjusted IRR 1.96; 95% CI 1.06–3.60) and patients with a T1b lesion (adjusted IRR 5.99; 95% CI 4.45–8.07). Recurrence was lower in patients aged >60 years (adjusted IRR 0.42; 95% CI 0.28–0.62) compared with those aged 0–39 years. There was no difference related to anatomical site.

In the 16 392 patients diagnosed from 2001 to 2010 (Fig. S1), the overall 5-year MSS was 99.66%. Comparing the group who did not undergo SLNB with those who had an SLNB, the rates were 99.66% and 98.92%, respectively (HR 2.30; 95% CI 0.74–7.20;

Table 2 Comparison of regional nodal recurrence versus no regional nodal recurrence in patients who did not undergo SLNB for T1 melanoma diagnosed from January 2001 to December 2015 in Queensland

	Observed total *n* = 27 584 (%)	No regional nodal recurrence *n* = 27 406 (%)	Regional nodal recurrence *n* = 178 (%)	Adjusted IRR (95% CI)†
Sex				
Male	15 344 (56)	15 227 (56)	117 (66)	1.65‡ (1.20–2.28)
Female	12 240 (44)	12 179 (44)	61 (34)	1.00 – Reference
Age (years)				
0–39	4179 (15)	4140 (15)	39 (22)	1.00 – Reference
40–59	10 006 (36)	9929 (36)	77 (43)	0.76 (0.51–1.12)
>60	13 399 (49)	13 337 (49)	62 (35)	0.42‡ (0.28–0.62)
Site				
Head/neck	4101 (15)	4071 (15)	30 (17)	1.00 – Reference
Trunk	10 522 (38)	10 453 (38)	69 (39)	0.85 (0.55–1.31)
Arm	7189 (26)	7147 (26)	42 (24)	0.82 (0.51–1.33)
Leg	5684 (21)	5648 (21)	36 (20)	0.86 (0.52–1.40)
Subtype				
SSM	18 407 (67)	18 296 (67)	111 (62)	1.00 – Reference
NM	442 (2)	431 (2)	11 (6)	1.96‡ (1.06–3.60)
NOS/other	8663 (31)	8607 (31)	56 (31)	1.10 (0.80–1.52)
Acral lentiginous	72 (<1)	72 (<1)	0 (0)	§n/a
Thickness (mm)				
0–<0.8	23 268 (84)	23 186 (85)	82 (46)	¶
0.8–1.0	4316 (16)	4220 (15)	96 (54)	¶
Ulceration				
Present	643 (2)	629 (2)	14 (8)	¶
Absent	26 941 (98)	26 777 (98)	164 (92)	¶
T-stage††				
T1a	22 902 (83)	22 823 (83)	79 (44)	1.00 – Reference
T1b	4682 (17)	4583 (17)	99 (56)	5.99‡ (4.45–8.07)

†IRR + 95% CI for risk factors associated with regional nodal recurrence. ‡Significance at $P < 0.05$. §Rate ratio could not be calculated as there were no cases of regional recurrence. ¶No statistical testing performed as interdependent with T-stage. ††T-stage as per the American Joint Committee on Cancer 8th Edition. CI, confidence interval; IRR, incidence rate ratio; NM, nodular melanoma; NOS, not otherwise specified; SLNB, sentinel lymph node biopsy; SSM, superficial spreading melanoma.

Table 3 The 5-year MSS for T1 melanoma in Queensland from January 2001 to December 2010 (n = 16 392) according to regional node observation versus SLNB

	Total cohort	No SLNB		SLNB		
		Nodal recurrence	Total	SLNB−	SLNB+	Total
Total T1	99.66 (56)	66.89 (49)†	99.66 (55)†‡	98.89 (1)	100 (0)	98.92 (1)‡
T1a	99.83 (23)§	67.69 (21)	99.83 (23)	100 (0)	100 (0)	100 (0)
T1b	98.90 (33)§	66.27 (28)	98.91 (32)	98.36 (1)	100 (0)	98.44 (1)

All figures are expressed as: MSS %. Values in parenthesis indicate raw number of deaths. †Significant ($P < 0.001$) difference between marked groups (HR 51.3). ‡Non-significant ($P = 0.149$) difference between marked groups (HR 2.30; 95% CI 0.74–7.20). §Significant ($P < 0.001$) difference between marked groups (HR 4.85; 95% CI 3.90–6.03). CI, confidence interval; HR, hazard ratio; MSS, melanoma-specific survival; SLNB, sentinel lymph node biopsy.

$P = 0.15$) (Table 3). For patients who did not have SLNB, there were 49 patients with nodal recurrence with a reduced 5-year MSS of 66.89 (T1a 67.69%; T1b 66.27%; HR 51.3; Table 3). Patients with a T1b primary lesion had a reduced 5-year MSS of 98.90% compared with 99.83% for patients with a T1a melanoma (HR 4.85; 95% CI 3.90–6.03; $P < 0.001$) (Table 3). The one death in the SLNB group had a negative SLNB.

Discussion

We report a population-based assessment of outcomes from the lymph node management of patients with pT1 primary cutaneous melanoma over a 15-year period in Queensland. Following wide local excision of the primary lesion, most patients (99.1%) did not undergo SLNB, with a regional recurrence rate of 0.6%. This represents 12 patients with a single thin primary melanoma requiring regional nodal dissection per year in Queensland. The recurrence rate was seven times higher in patients with a T1b lesion (2.1%) compared with T1a (0.3%). This was confirmed as an independent risk factor for recurrence along with male gender and nodular subtype.

The rate of SLNB was highest in patients with T1b lesions, with this group having a positive sentinel node in 7.2% of cases. The reasons for the disparity in the SLNB positive rate and clinical nodal involvement rate are not clear. There is likely to be a significant degree of selection bias towards SLNB for the small subset in this study. Another factor may relate to the median follow-up time for the observed cohort. In the MSLT-I trial patients with a melanoma of 1.2–3.5 mm thick, the nodal recurrence rate for the group who did not undergo SLNB progressively approached the SLNB positive rate with increasing time,[9] so that by 10 years, the clinical nodal involvement in the observed group was 2.4% less than the SLNB positive rate. At 7 years, the difference appears to be 3.7% higher in the SLNB group[9] (measured from the figure in the study). MSLT-I did not include detailed data for patients with a melanoma <1.2 mm.

The literature suggests that an SLNB positive rate of 5% justifies the procedure due to its low morbidity[9,10] and prognostic value.[1] Our results, from patients selected to have SLNB, would support considering the procedure for pT1b lesions, with particular emphasis on the group 0.8–1.0 mm with ulceration, where the positive rate was 17.6%. A recent large cohort study from the USA reported a series of patients with AJCC 8th Edition pT1b melanoma in which the SLNB rate was 88%.[15] When assessing those patients with thickness of 0.8–1.0 mm without ulceration, 55% had a positive node rate <5%.[15] There were two groups with a positive rate >5%: patients aged <56 years with mitoses ≥1/mm^2 and those >56 years who had a thickness of 1 mm and mitoses ≥1/mm.[15] With a focus on the biology of the lesion, others have also reported a significant role for mitoses in identifying an adverse prognosis.[16–18] When assessing the risk for nodal involvement in patients not having SLNB, another study from the USA reported a regional recurrence rate consistent with our study, and similarly identified higher risk in males, younger age and increased Breslow thickness.[13] There is a need for larger studies that will more clearly identify the subset of T1 melanoma patients for which the utility and benefits of SLNB are better defined. This is also likely to include tumour factors as yet to be defined.

The AJCC 8th Edition stratification of T1 melanoma is supported by this study, with a T1b melanoma patient found to have nearly a five times higher risk of dying from melanoma at 5 years (albeit 1% difference) and a higher risk of regional nodal recurrence. The survival rates we report are similar to those reported in the AJCC 8th Edition manuscript.[8] We found no difference in the MSS between patients with a T1b melanoma who did, or did not, have SLNB. There were no deaths in our SLNB-positive group; however, we confirm the negative impact from clinical regional nodal involvement with a significant reduction in 5-year survival (67%). The AJCC 8th Edition staging now combines T-stage with nodal status such that a T1a or T1b melanoma with one to three positive sentinel nodes is classified as stage IIIA. The reported 5-year survival is 93%,[8] being higher than a recent study from Spain, which reported the 5-year survival for 203 patients with T1b melanoma and a positive SLNB to be 75%.[17]

Recently, adjuvant therapy trials have reported improved progression-free survival for patients with stage III melanoma, including patients with a positive SLNB.[19–22] However, analysis of one of the trials found a limited effect from immunotherapy in AJCC 8th Edition stage IIIA patients.[23] If sentinel node positivity does not influence access to adjuvant therapy, and with no impact on survival, clinician uncertainty for the role of SLNB in T1 melanoma patients seems reasonable. There are clear subsets of patients with T1 melanoma who have a higher risk of nodal involvement, so that there is an imperative to better define these patients for prognostic information, particularly as the indication for adjuvant therapy evolves in the future.

The strength of this study is the large number of patients assessed at a population level. The limitations include the small number who

had an SLNB, along with the low number of positive cases and low death rate, which reduced the ability to better assess the SLNB group. The regional recurrence rate for the group of patients that did not undergo SLNB was derived from hospital records and pathology rather than direct knowledge. Univariate regression was utilized to compare survival between groups due to difficulties developing a robust multivariate analysis model with the small number of overall deaths.

In conclusion, patients with a T1 melanoma have an excellent survival, with a low risk of nodal involvement. However, subsequent clinical nodal recurrence carries a much worse prognosis. Patients with AJCC 8th Edition pT1b melanoma comprised 17% of all thin melanomas and are confirmed in this study as having a significantly worse MSS at 5 years and higher risk of regional nodal recurrence, with the highest nodal involvement in those with a melanoma of 0.8–1.0 mm with ulceration. Aside from this subset of patients, continued assessment aiming to define other high-risk factors for nodal involvement and worse survival outcomes in patients with a T1 melanoma needs to occur.

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Conflicts of interest

None declared.

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Supporting information

Additional Supporting Information may be found in the online version of this article at the publisher's web-site:

Figure S1. Display of melanoma diagnoses from January 2001 to December 2015 in Queensland. The American Joint Committee on Cancer 8th Edition staging was used.

Table S1. Demographic and pathological characteristics of T1 melanoma diagnosed from January 2001 to December 2015 in Queensland.