

Jennifer Downs ORCID iD: 0000-0001-7544-6021
Suren Subramaniam ORCID iD: 0000-0002-9821-0270
Andrew Spillane ORCID iD: 0000-0002-8354-434X

A Survey of Surgical Management of the Sentinel Node Positive Melanoma Patient in the post-MSLT2 Era

Jennifer S Downs MBChB FCS(SA)¹
Suren Subramaniam MMBS FRACS¹
Michael A Henderson MD FRACS^{1,2}
Elizabeth Paton, BLAS³
Andrew J Spillane MD FRACS^{4,5,6}
Jon A Mathy MD FACS FRACS^{7,8}
David E Gyorki MD FRACS^{1,2}

Affiliations:

1. Peter MacCallum Cancer Centre, Melbourne, Victoria, Australia
2. University of Melbourne, Melbourne, Victoria, Australia
3. Melanoma and Skin Cancer Trials Ltd, Monash University, Melbourne, Victoria, Australia
4. Melanoma Institute Australia, The University of Sydney, Sydney, New South Wales, Australia
5. Royal North Shore Hospital, St Leonards, Sydney, New South Wales, Australia
6. Mater Hospital, Wollstonecraft, Sydney, NSW Australia
7. Auckland Regional Plastic Surgery Unit, Auckland, New Zealand
8. University of Auckland, Auckland, Australia

Corresponding author: A/Prof David Gyorki

David.gyorki@petermac.org

+61385597740

Peter MacCallum Cancer Centre

305 Grattan Street

Melbourne, Victoria

Australia

3000

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Running head: survey surgical management of sentinel node positive melanoma

Synopsis: a survey of surgical management of the sentinel node positive melanoma shows a significant shift in practice in line with recent publications and widening access to effective systemic therapy.

Abstract

Background: The evidence-based management of melanoma patients with a positive sentinel lymph node biopsy (SLNB) has undergone a dramatic shift following publication of practice changing surgical trials demonstrating no melanoma specific survival advantage for completion lymph node dissection (CLND) in this scenario. We aimed to survey how surgeons' clinical practice had

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shifted in response to new evidence from these trials, and at a time when there was starting to become available systemic adjuvant treatments for AJCC Stage 3 melanoma patients.

Methods: A web-based survey consisting of practice-based questions and hypothetical clinical scenarios about current melanoma practice with regards to positive sentinel node biopsy was developed and sent to the surgical members of a Melanoma and Skin Cancer (MASC) trials group in December 2018. Responses were analysed using descriptive statistics.

Results: There were 212 invitations sent and 65 respondents (31%). Respondents were from 17 countries, 94% of whom practice in specialist melanoma centres or at referral centres. Of these 97% were familiar with the MSLT-2 and DeCOG-SLT clinical trials. At survey 5% of respondents reported routinely recommending completion lymph node dissection (CLND) and 55% recommend CLND in selected cases. Respondents were most likely to recommend CLND when multiple SLNs were positive. Important factors for surgical decision-making mentioned included size of SLN deposit, number of positive SLNs and likely compliance with the recommended surveillance regimen.

Conclusion: In line with rapid adoption of published evidence, surgical management of stage III melanoma has altered significantly, with few surgeons within the cohort now performing routine CLNDs after positive SLNB.

Introduction

In recent years, the management of patients with sentinel lymph node (SLN) positive melanoma has undergone a paradigm shift, with the publication of practice-changing reports defining surgical management as well as the introduction of effective systemic therapies[1].

Two landmark trials were published in 2016 and 2017 (Complete Lymph Node Dissection vs No Dissection in Patients with Sentinel Lymph Node Biopsy Positive Melanoma(DeCOG-SLT) and Multicentre Selective Lymphadenectomy Trial2(MSLT2))[2,3]. Both studies randomized patients with SLN positive melanoma to immediate completion lymph node dissection (CLND) versus regular ultrasound and clinical surveillance of the draining lymph node basin with delayed CLND at the time of isolated lymph node progression. Both studies had consistent results demonstrating no difference in melanoma specific survival. The DeCOG SLT study also showed no difference in recurrence free survival. Although MSLT-2 did show a small improvement in recurrence free survival after CLND, this did not translate into an overall survival advantage[2].

In 2012, during the recruitment phases of these trials, an international survey showed that the vast majority (91.8%) of surgeons favoured immediate CLND for patients with SLN positive melanoma[4]. Using data from that previous survey as a base line comparator, we aimed to assess the degree of changes in international practice following the publication of these novel data, specifically with regards to the surgical management of patients with a positive SLN.

Methods

A melanoma survey questionnaire (Appendix 1) was developed by a team of surgeons practicing in an Australian academic tertiary referral center. Using the 2012 survey as a starting point, a new survey of questions relevant to current melanoma practice was developed[4]. Melanoma The survey questions were reviewed within the unit for clarity and relevance. Survey participants with a primary discipline of surgical oncology, general surgery or plastic surgery were identified from the Australia New Zealand Melanoma trials group (ANZMTG)

membership database (ANZMTG was subsequently renamed Melanoma and Skin Cancer Trials – MASC Trials in 2018). Ethics approval was obtained from the Sydney Local Districts Ethics Review Committee.

Of the 1484 members of MASC, 212 were identified with primary/secondary discipline as Surgery/Plastic surgery. A survey was created on the SurveyMonkey internet platform. Questions were divided into 2 sections – The first included questions designed to assess the surgeons' general and clinical profile and experience as well as their insight into recent publications. The second section included four hypothetical clinical scenarios created to interrogate various aspects of care for patients with SLN positive melanoma.

The survey link was sent in December 2018 and remained open for three weeks. Two further reminders were sent during this time.

All statistical analyses were performed in R (R version 3.6.3 (2020-02-09)) using standard and validated statistical procedures. The questionnaire data were analysed using descriptive statistics. Quantitative variables were compared using Wilcoxon test; qualitative variables were compared using Fisher's exact test.

Results

Sixty-five responses from 17 countries were analysed (response rate 31%). Of the respondents, 48% identified themselves as general surgeons, 28% as surgical oncologists and 24.6% as plastic surgeons. Almost all (95.4%) respondents' principal place of practice was a specialist melanoma centre or tertiary referral centre. Geographical locations of the respondents were widespread, including Australia/New Zealand (38.5%), Europe (26.2%), United Kingdom (15.4%), USA/Canada (13.8%) and South America (7.7%). The majority of respondents had large melanoma practices, with 68% performing more than 20 SLNBs per year, 20% between 10-20 SLNBs and 13% less than 10 SLNBs a year.

Melanoma tumour board meetings were almost universally accessible (97%) and 84% of respondents were regular participants. 78% of respondents indicated that all stage III melanoma cases were discussed at their tumour board and of the remainder nearly all indicated that only difficult cases were discussed.

All but two respondents reported being familiar with the results of MSLT-2 and DeCOG-SLT. When answering the question 'for patients with a positive SLNB, I recommend immediate completion lymphadenectomy rarely, selectively or routinely', 40% of responding surgeons chose 'rarely', 55% of surgeons chose 'selectively' and 5% chose 'routinely'. There was no uniformity amongst those who 'routinely' offer CLND with regards to geographic location, size of practice, proportion of practice being stage III patients or participation in an MDM. Responses to the questionnaire were then stratified into two groups based on this response.

Table 1: General information by reported Completion Lymph Node Dissection (CLND) recommendation frequency

General information is summarized in Table 1 by the frequency of the surgeon's CLND recommendation. Sixty eight percent of respondents performed over 20 SLNs per year; 50% of these surgeons selectively or routinely recommend CLND. Of the 13 surgeons who perform 10 to 20 SLNs per year, only one rarely recommends CLND, while the rest recommend it selectively or routinely. All surgeons (25 of 25) who reported they rarely recommended CLND also reported they are regular participants in a Melanoma MDM (weekly or fortnightly). All surgeons who discuss cases 'as needed' at an MDM, don't use an MDM or don't have access to one selectively or routinely recommend CLND. Surgeons with a

larger proportion of stage III patients were more likely to report that they rarely recommend CLND (median [IQR]: 30% [20, 45] vs 20% [15, 30], $p=0.025$).

Table two: Comparison of results between 2012 and 2018 surveys

Comparison of the two groups of respondents in the 2012 and 2018 surveys shows a broad geographic spectrum of respondents[4]. This distribution was similar across the two groups assessed, although there is a higher percentage of respondents from Australia and New Zealand in the 2018 group. More respondents in the 2018 group practiced at melanoma specific centres. Over six years, the number of surgeons recommending routine CLND dropped by 86.8%.

Table three: Summary of influential factors by reported Completion Lymph Node Dissection (CLND) recommendation frequency

A broad range of factors were regarded as important when making a decision about management of the SLN+ lymph node basin, with no clear consensus. However, the most commonly cited factors were size of the SLN deposit (63%), total number of involved LNs (52%) and ability to comply with surveillance (42%). The site of LN basin involved, primary tumor characteristics, patients' age, body habitus, and total number of excised LNs were considered less important.

When the factors regarded as important in decision making were compared between the 2012 and 2018 surveys, concern about the volume and extent of disease in the nodal basin is unchanged as two of the top factors cited when making decisions regarding CLND. Patient compliance with surveillance was the third most cited factor in 2018, which was not assessed in 2012. In 2012, patient comorbidities was the most commonly cited factor in decision making about CLND.

Four clinical scenarios were generated to further probe respondent's reactions to 'real world' scenarios (supplementary table), and how they apply the MSLT2 findings to these patients. All staging listed is from the AJCC 8th edition[5].

The surgeons were asked to review four scenarios and asked to either recommend CLND or surveillance.

Scenario 1: 43-year-old male with a T2a melanoma of the leg, 1/2 SLN with 1.2mm deposit (stage IIIA).

Scenario 2: 65-year-old male with a T3b melanoma of the cheek, 1/3 SLN with 0.8mm subcapsular deposit (stage IIIC).

Scenario 3: 70-year-old female with a T4b melanoma of the back, 1/1 SLN with 2mm parenchymal deposit (stage IIIC).

Scenario 4: 39-year-old male with a T2a melanoma of the scalp, 2/2 SLN with 0.8mm and 1mm deposits respectively.

Table four: Answers to scenarios 1-4 by reported Completion Lymph Node Dissection (CLND) recommendation frequency

Table four stratifies the answers to the given scenarios by previously answered CLND recommendation frequency. Although progressively more respondents in both the rarely and selectively/routinely groups chose CLND in each scenario, they were not always the same group of respondents. Choosing to do a CLND for the patient in Scenario One did not imply that CLND was chosen through the rest of the scenarios. Of those who chose to surveil the

patient in Scenario four (the scenario with the largest number of recommendations for CLND), one recommended CLND in Scenario one, one recommended CLND in Scenario two, and six recommended CLND in Scenario three.

When reviewed separately, those who answered that they routinely recommended CLND, did not always recommend CLND when responding to the clinical scenarios.

Table five: scenario answers recommended by country of respondent (DNA - did not answer)

Table five stratifies the responses to scenarios by country of practice of the respondent. The proportion of 'did not answer' (DNA) remains relatively constant in both groups across all scenarios. Surveillance was more widely recommended by Australia/New Zealand and North American groups of surgeons. However, all groups had higher proportions recommending CLND in the latter two scenarios compared to the former.

Discussion:

This is one of the first studies to attempt to quantify the change in contemporary surgical management of patients with positive SLN in response to practice changing evidence. The practice of evidence-based medicine is essential to modern surgery, but surgeons have multiple influences. Prior training, location of practice, and memories of previous good or bad outcomes all influence surgeon behaviour[6]. Therefore, practice changes cannot be expected to be adopted uniformly.

The study respondents are voluntary members of MASC Trials, a melanoma trials group. More than 90% perform more than ten SLNs for melanoma annually. The vast majority participate in a broadly representative multidisciplinary melanoma meeting, implying their influence on local melanoma management. Although not all respondents practiced high volume melanoma care, their responses were sought as this survey attempted to cover a broad range of practices.

The respondents represent 17 countries around the world. This means that local variations in practice are balanced out by a wider range of countries represented.

Almost all respondents were familiar with the results of MSLT2 and DeCOG-SLT. Unlike the previous study in 2012, only five percent of surgeons still routinely recommended CLND. Although respondents were asked if they were familiar with the results of MSLT2, they were not asked to what extent they agreed with the conclusions of the trial or planned to apply it to their own practice. Over half of the respondents still selectively use immediate CLND, despite the lack of high-level evidence to support this practice[2]. A recent retrospective study confirmed this change in practice, with 86% of patients in their post publication of MSLT-2 cohort of 965 positive SLNBs receiving active surveillance[7].

The surgeon population was analysed according to those who routinely/selectively recommend CLND compared to those who rarely do. In this small sample, demographic factors that were significantly different between the two groups were limited. Type of surgical specialty, location and country of practice, MDM discussion and proportion of patients in the practice requiring sentinel node staging were not significantly different.

Surgeons who performed more than 20 SLNs per year were more likely to rarely recommend CLND, indicating that surgeons with a larger melanoma practice were more like to have shifted their practice in line with the results of MSLT-2 and DeCOG-SLT. Surgeons who rarely recommended CLND also stated a larger proportion of stage 3 melanoma patients in their practice. Interestingly, although the majority of surgeons recommending selective or routine CLND regularly participate in MDM, all the surgeons who rarely recommend CLND are regular participants. This suggests that surgeons who have a large melanoma practice and regularly discuss management with other relevant specialties have shifted their practice in line with current guideline recommendations.

When considering immediate CLND, the three most important factors the respondents reported as likely to influence their decision were: size of the SLN deposit, number of positive SLNs involved and the ability of the patient to comply with the surveillance, respectively. These concerns remained relatively unchanged since 2012, with the significant addition of concern about patients' ability to be compliant with the recommended surveillance regimen. Of note, the MSLT2 trial specified that there were no statistically significant differences in survival on multivariate analysis when analyzing for the number of positive sentinel LNs or the size of the SLN deposit[2]. Furthermore, recent data suggests that immediate CLND provides minimal prognostic stratification beyond their initial surgery for patients with SLN positive melanoma[8]. However, from answers to the clinical scenarios it can be inferred that a higher burden of disease in the sentinel lymph node is associated with a greater willingness of surgeons to recommend CLND.

These scenarios were created with a view to test clinical decision making particularly in situations where immediate CLND would have previously been considered standard of care[9]. The scenario with the highest reported CLND rate (48%, scenario 4) involved a young patient with T2a melanoma of the head and neck with multiple involved nodes. This is the patient who objectively has the most to gain from immediate CLND with the lowest rate of distant metastatic spread and highest risk of further regional lymphadenopathy([10].

Interestingly, in scenario 3, in which an older patient with a T4b melanoma has a high sentinel node tumour burden, 40% of respondents recommended immediate CLND. This is despite the high risk of distant metastatic disease in this patient[11].

Only three respondents recommended immediate CLND in all scenarios. Choosing CLND in scenario one did not indicate that CLND would be advised for other scenarios. There were respondents who, despite recommending surveillance for scenario four, the most commonly chosen scenario where CLND was recommended, chose CLND in other scenarios. This fits with the wide range of patient and tumour factors quoted as influential by respondents, and their consideration in clinical decision-making.

This survey was undertaken less than 2 years after publication of MSLT2, and it is possible that as respondents become more accustomed to nodal surveillance, they will apply it more widely. It requires frequent follow up as well as regular imaging, and compliance and cost outside of the trial setting are real considerations. Furthermore, this survey was released only 12 months after the publication of the AJCC 8th edition and clinician familiarity with the staging system may not have been complete. This is particularly important as the 8th edition incorporates the prognostic significance of the primary melanoma in those patients with lymph node positive disease, which can upstage patients with high risk primary melanoma from stage IIIA (7th edition[12]) to stage IIIC (8th edition[5]).

The advent of novel immunotherapies and targeted treatments revolutionized systemic therapy of melanoma in both cases of advanced disease as well as in the adjuvant setting [13–16]. The use of adjuvant therapies has doubled relapse free survival for patients with stage III melanoma and early data suggests a major impact on overall survival as well [15,17]. These considerations were not taken into account in the survey although undoubtedly influenced the decision making of the respondents. At the time of the survey, access to adjuvant therapy was highly variable in various parts of the world. The access to these therapies may have influenced the decision making of the participating surgeons.

There were several limitations of this study. Although a 30% response rate to a survey is acceptable, it is a small sample size which may not be reflective of broader international practice. Respondents were part of a melanoma trials group, which may have made them more likely to rapidly adopt new practices. The survey was not piloted prior to release and was not designed by specialists in qualitative research. There were no versions in languages other than English. The questions it raised are complex and patient management should be individualised, which made simplifying this into a brief survey challenging.

Conclusion

These results highlight a dramatic shift in practice following the publication of MSLT2 and DeCOG-SLT with only 5% of surgeons routinely recommending immediate CLND following a positive SLNB, down from 92% in 2012[4]. However, there remains hesitation to apply the results of these studies routinely. This survey shows that the paradigm shift of melanoma treatment towards less aggressive surgery and increased reliance on systemic therapies has been more slowly accepted and applied than was previously assumed. This

group of respondents, active research contributors, could be assumed to be at the forefront of adopting new evidence-based practices. The hesitation demonstrated by the continued recommendation of immediate CLND means that further work is required. Publication of real-world results of following MSLT2 derived guidelines could be helpful to convince surgeons. This survey also highlights the importance of high-quality evidence-based guidelines to rapidly respond to new evidence to support changing practices.

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Data availability statement: The data that support the findings of this study are available from the corresponding author upon reasonable request.

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Table 1: General information by reported Completion Lymph Node Dissection (CLND) recommendation frequency

Characteristic	Recommended CLND			p-value
	Rarely (n = 25)	Selectively/Routinely (n = 40)	Total (n = 65)	
Primary specialty				
General surgeon	13 (39%)	20 (61%)	33	>0.999 ¹
Head & Neck/ENT	6 (38%)	10 (62%)	16	
Plastic surgeon	6 (40%)	9 (60%)	15	
Dermatologist	0	1 (100%)	1	
Place of practice				
Specialist melanoma centre	16 (40%)	24 (60%)	40	0.515 ¹
Tertiary hospital	9 (41%)	13 (59%)	22	

District hospital	0	3 (100%)	3	
Country				
Other	16 (39%)	25 (61%)	41	>0.999 ¹
Australia/New Zealand	9 (38%)	15 (62%)	24	
Number of sentinel node biopsies performed per year				
>20	22 (50%)	22 (50%)	44	0.012 ¹
10-20	1 (8%)	12 (92%)	13	
<10	2 (25%)	6 (75%)	8	
Proportion of melanoma patients who receive sentinel node biopsies				
>95%	11 (35%)	20 (65%)	31	0.118 ¹
81-95%	8 (62%)	5 (38%)	13	
50-80%	5 (42%)	7 (58%)	12	
<50%	1 (11%)	8 (89%)	9	
Access to melanoma MDM				
Regular participant	25 (46%)	29 (54%)	54	0.026 ¹
Discuss as needed	0	6 (100%)	6	
Have access, but not used	0	3 (100%)	3	
No access	0	2 (100%)	2	
Proportion of cases that are stage III				
Mean (SD)	33.2 (15.3)	24.6 (14.7)	28.0 (15.4)	0.025 ²
Median [range]	30.0 [10.0 - 60.0]	20.0 [0.0 - 60.0]	25.0 [0.0 - 60.0]	
IQR	20.0 - 45.0	15.0 - 30.0	20.0 - 40.0	
Missing	0	1	1	
MDM discussion stage III				
All cases	19 (39%)	30 (61%)	49	0.753 ¹
Difficult decision	6 (46%)	7 (54%)	13	
Missing	0	3	3	
Familiar with MSLT 2 results				
Yes	25 (40%)	38 (60%)	63	>0.999 ¹
No	0	1 (100%)	1	
Missing	0	1	1	

1 - Fisher's Exact test
2 - Wilcoxon test

Table 2 Comparison of results between 2012 and 2018 surveys

Characteristics	2012 N=184	2018 N=66
Geographic distribution		
Australia/New Zealand	11.4%	38.5%
Europe (incl UK)	56.4%	41.6%
North America	24.3%	13.8%
South America	4.6%	7.7%

Asia	3.1%	0%
Africa	0%	0%
Expertise of primary place of practice		
Melanoma Specific centre	30.1%	61.5%
Referral surgical oncology centre	44.6%	33.8%
General surgery /District/community centre	25.3%	6.1%
Recommend CLND routinely	91.8%	5%

Table three: Summary of influential factors by reported Completion Lymph Node Dissection (CLND) recommendation frequency

Characteristic	Recommended CLND		
	Rarely (n = 25)	Selectively/Routinely (n = 40)	Total (n = 65)
Influential factors[†]			
Size of nodal deposit	15 (60%)	26 (65%)	41 (63%)
Number of nodes involved	10 (40%)	23 (57%)	33 (51%)
Compliance	11 (44%)	16 (40%)	27 (42%)
Location of nodal basin	10 (40%)	9 (22%)	19 (29%)
Primary tumour characteristics	3 (12%)	14 (35%)	17 (26%)
Age	4 (16%)	9 (22%)	13 (20%)
Other	7 (28%)	4 (10%)	11 (17%)
Body habitus	3 (12%)	4 (10%)	7 (11%)
Number of excised nodes	0	5 (12%)	5 (8%)

Table four: Answers to scenarios 1-4 by reported Completion Lymph Node Dissection (CLND) recommendation frequency

Characteristic	Recommended CLND		
	Rarely (n = 25)	Selectively/Routinely (n = 40)	Total (n = 65)
Scenario 1			
CLND	0	12 (34%)	12 (22%)
Surveillance	19 (100%)	23 (66%)	42 (78%)
Missing	6	5	11

Scenario 2			
CLND	2 (11%)	9 (31%)	11 (23%)
Surveillance	17 (89%)	20 (69%)	37 (77%)
Missing	6	11	17
Scenario 3			
CLND	3 (17%)	16 (53%)	19 (40%)
Surveillance	15 (83%)	14 (47%)	29 (60%)
Missing	7	10	17
Scenario 4			
CLND	6 (29%)	19 (61%)	25 (48%)
Surveillance	15 (71%)	12 (39%)	27 (52%)
Missing	4	9	13

Table five: scenario answers recommended by country of respondent

	Aus/NZ(n=25)	USA/Canada(n=9)	Other(n=32)
Scenario one -			
43M T2a leg, 1/2 SLN 1.2mm deposit (IIIA)			
CLND	2 (8%)	2(22%)	8(25%)
Surveillance	18(72%)	7(78%)	17(53%)
DNA*	5(20%)	0(0%)	6(19%)
Scenario two –			
65M T3b face, 1/3 SLN 0.8mm deposit (IIIC)			
CLND	2(8%)	1(11%)	8(25%)
Surveillance	17(68%)	8(89%)	12(37%)
DNA	6(24%)	0(0%)	12(37%)
Scenario three			
– 70F T4b trunk, 1/1 SLN 2mm deposit (IIIC)			
CLND	5(20%)	3(33%)	11(34%)
surveillance	14(56%)	6(67%)	9(28%)
DNA	6(24%)	0(0%)	10(31%)
Scenario four –			
39M T2a scalp 2/2 SLN 0.8mm and 1mm deposits (IIIA)			
CLND	9(36%)	4(44%)	12(37%)
Surveillance	10(40%)	5(56%)	12(37%)
DNA	6(24%)	0(0%)	8(20%)

* did not answer

Appendix 1

The surgeons were asked to review 4 scenarios and asked to either recommend CLND or surveillance, and whether or not they would recommend adjuvant therapy.

Scenario 1: 43 year old male with 1.4mm thick, non-ulcerated melanoma of the lower leg found on excision biopsy with a narrow margin. Wide excision and sentinel lymph node biopsy (two superficial inguinal nodes removed) showed no residual melanoma in the excision specimen; SLNB revealed 1.2mm focus of melanoma metastasis in single lymph node without extranodal extension; 2nd LN negative (stage IIIA).

Scenario 2: 65 year old male with 2.7mm thick, ulcerated melanoma of the left cheek on excision biopsy. Wide excision with SLNB (three lymph nodes removed from level IIA of the neck) was done. Histopathology demonstrated no residual melanoma in the excision specimen; SLNB revealed 1 out of 3 nodes with an 0.8mm subcapsular deposit (stage IIIC).

Scenario 3: 70 year old female presents with a pigmented lesion on her back. Excision biopsy confirms this to be 6.1mm thick nodular, ulcerated melanoma. She proceeded to have a wide excision and SLNB from both axillae (right axilla - one lymph node removed; left axilla - one lymph node removed). Histopathology showed no residual melanoma in the wide excision specimen; Right axillary sentinel node was negative, but the left axillary sentinel node showed a 2mm parenchymal deposit of melanoma (1/1 (Stage IIIC)).

Scenario 4: 39 year old male with 1.9mm thick, non-ulcerated melanoma of the temporal scalp 3cm superior to the pinna on the left side, excised with a narrow margin. Wide excision and sentinel node biopsy done (two sentinel nodes from level II and level V of the left neck); Histopathology shows no residual melanoma in the wide excision specimen; SLN from level II contains a 0.8mm subcapsular deposit, SLN from level V contains a 1mm subcapsular deposit. No extranodal extension is seen (stage IIIA).