Melanoma nodal management in Ontario the year after the 2012 American Society of Clinical Oncology and Society of Surgical Oncology guideline

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ABSTRACT

Background  In 2012 in the United States, the American Society of Clinical Oncology and the Society of Surgical Oncology (ASCO/SSO) published a joint guideline about indications for sentinel lymph node biopsy (SLNB) in cutaneous melanoma. The guideline supported completion lymph node dissection (CLND) for all patients with positive sentinel nodes. We examined the rates and predictors of SLNB and CLND for melanoma patients in Ontario (population 13.6 million) after publication of that guideline.

Methods  We used the Ontario Cancer Registry to identify patients diagnosed with cutaneous melanoma in 2013. Patient records were linked to prospectively maintained health administrative databases to obtain details for each patient, including surgical procedures.

Results  Of the 3298 patients with melanoma identified in Ontario in 2013, 1973 (59.8%) could be analyzed. Most of that group (n = 1227, 62.2%) underwent local excision alone; 746 (37.8%) had a SLNB. The SLNB was performed in 13.9%, 67.8%, 62.6%, and 47.2% of patients with T1, T2, T3, and T4 primary melanomas respectively. In multivariate analysis, receipt of SLNB was positively associated with younger age (<80 years), higher T stage, and a non-head-and-neck primary. Of the patients who had a SLNB, 136 (18.2%) were found to be node-positive. A CLND was performed in 82 of those patients (60.3%).

Conclusions  In Ontario, only two thirds of patients with intermediate-thickness melanomas (T2, T3) underwent SLNB as recommended by the ASCO/SSO guideline. Use of SLNB was less frequent for patients with a head-and-neck primary and higher for younger patients (<80 years). The rate of CLND after a positive SLNB was also low relative to the guideline recommendation.

Key Words  Melanoma, sentinel lymph node biopsy, lymph node dissection, population-based research

INTRODUCTION

Although identification of patients with clinically occult nodal metastases in melanoma was known to be important for prognosis and perhaps for therapeutic benefit, it was not until 1989, with the publication of the Morton et al. case series of sentinel lymph node biopsy (SLNB), that identification could be accomplished simply, accurately, and with low morbidity. In 2006, the first results of the Multicenter Selective Lymphadenectomy Trial I (MSLT-I) were published. Although the overall results showed no survival benefit when observation was compared with SLNB, subgroup analysis identified a significant survival advantage of SLNB for the early detection and treatment of nodal disease.

In 2012 in the United States, the American Society of Clinical Oncology and the Society of Surgical Oncology (ASCO/SSO) released a joint guideline recommending the use of SLNB for intermediate-thickness melanomas.
Although the guideline also suggested that thick melanomas "may be" recommended for SLNB, they acknowledged the lack of data and controversy about the benefits. Routine use of SLNB was not recommended for thin melanomas. The guideline further supported completion lymph node dissection (CLND) for all patients with positive sentinel nodes.

For the purpose of quality assurance in melanoma management in Ontario, we examined the rates and predictors of receipt of SLNB and CLND in the presence of a positive sentinel node for melanoma patients, with an emphasis on guideline adherence. A better understanding of receipt of SLNB and CLND will allow for more targeted interventions to address any disparities in procedure rates compared with the guideline recommendations.

METHODS

Design and Setting
This population-based retrospective cohort study used health care administrative data from the province of Ontario (population 13.6 million). All Ontario residents obtain health care services from a government-administered single-payer system. A unique encoded identifier allows for linkages across several administrative databases, which were analyzed at ICES (https://www.ices.on.ca/). The study was approved by the research ethics board at Sunnybrook Health Sciences Centre (Toronto, ON). Participant informed consent was not required. This report follows the RECORD (Reporting of Studies Conducted Using Observational Routinely Collected Health Data) statement.

Data Sources
Databases included the Discharge Abstract Database (in-hospital procedures and diagnoses) maintained by the Canadian Institute for Health Information, the medical claims database (contains physician billing claims and diagnoses) maintained by ohip (the Ontario Health Insurance Plan), the Registered Persons Database (contains sociodemographic information and death certificates), and the Ontario Cancer Registry (prospectively identifies and obtains information from multiple sources for all newly diagnosed cases of invasive neoplasia). Through these databases, the universal single-payer health care system in Ontario can capture details for all health care encounters, hospitalizations, and procedures for all patients treated for melanoma. International Classification of Diseases for Oncology codes were used to identify all diagnoses and procedures. A description of the dataset is presented in supplementary Table 1.

Study Sample
The ocr was used to identify all patients 18 years of age and older with a melanoma diagnosis date of 1 January 2013 through 31 December 2013 (Figure 1). That period marks the first year after introduction of the asco /sso guideline and the availability of collaborative staging information for patients with melanoma in the ocr. In the ocr, patients with melanoma were identified using International Classification of Diseases for Oncology, revision 3, topography codes and morphology codes for melanoma (supplementary Table 2 shows the code lists). Patients were excluded if their cancer stage was recorded as either 0, iv, unknown, or missing. Further data cleaning was also conducted. Records were excluded if age was missing or less than 18 years, if patients were identified as non-Ontario residents on their diagnosis date, or if the patient’s recorded death date preceded the diagnosis date. The ohip medical claims database was used to determine whether patients underwent a SLNB and a regional node dissection (see supplementary Table 3 for the relevant codes). Patients who had a regional node dissection without a prior SLNB were excluded from the cohort because those patients likely had involved nodes that were clinically apparent. Patients with more than 1 melanoma diagnosed in the year were excluded from the cohort because the location of the SLNB—and hence the lesion for which it was performed—could not be reliably established.

Outcomes: SLNB and CLND
The primary outcome was receipt of SLNB within 6 months after the melanoma diagnosis date in the ocr. For the cohort of patients with a positive sentinel node, a secondary outcome was receipt of CLND within 6 months of the SLNB.

Patient, Tumour, and Treatment Factors
The patient characteristics analyzed were age, sex, comorbidities (Charlson comorbidity index) based on records from the 5-year period preceding the index diagnosis date. We used the patient’s primary residence (postal code) to determine a census-defined neighborhood-level income quintile and to define rural residence.

FIGURE 1 Study flow diagram. IKN = ICES identification number.
Tumour characteristics were defined based on the ocr. The \( T \) stage was characterized based on the American Joint Committee on Cancer staging manual, version 7.

**Statistical Analysis**

Patient, tumour, and treatment characteristics are described based on receipt and non-receipt of slnb for the whole cohort and then receipt and non-receipt of clnd for the sentinel-node-positive cohort. Where appropriate, characteristics are presented as means with standard deviation, medians with interquartile range, or proportions. Comparisons for continuous variables were made using the Student \( t \)-test or the Kruskal–Wallis test. A chi-square test was used for categorical variables. All descriptive analyses were performed using the software application SAS Enterprise Guide for UNIX (version 7.12: SAS Institute, Cary, NC, U.S.A.). A \( p \) value less than 0.05 was considered statistically significant. Univariate analysis was used to examine receipt of slnb as well as receipt of clnd for patients with a positive slnb. Logistic regression modelling was used to determine the association between patient and tumour characteristics and receipt of slnb.

**RESULTS**

**Patients**

Using the ocr, we identified 3412 cutaneous melanomas diagnosed in 3298 patients between 1 January 2013 and 31 December 2013. After all exclusions, as shown in Figure 1, the final cohort consisted of 1973 patients with melanoma.

**SLNB**

Of the 1973-patient cohort, 746 (37.8%) underwent slnb, and 1227 (62.2%) did not undergo slnb. Table i presents baseline patient and tumour characteristics for the overall cohort and for the groups undergoing and not undergoing slnb. Sentinel lymph node biopsy was performed in 13.9%, 67.8%, 62.6%, and 47.2% of the patients with \( T1 \), \( T2 \), \( T3 \), and \( T4 \) primary melanomas respectively.

By age group, slnb remained relatively consistent, except for a significant difference for the patients more than 80 years of age, only 18.4% of whom underwent slnb. Income quintile was not associated with the slnb rate, except, perhaps, for a nonsignificant trend in the lowest quintile. Rurality similarly showed no association with the slnb rate. A score on the Charlson comorbidity index could not be calculated for most patients in the overall cohort (70.8%) because they had not been hospitalized in the preceding 5 years. Where comorbidity could be estimated, patients with more comorbidities were less likely to undergo slnb. In patients with a head-and-neck primary, the slnb rate, at 20.7%, was half that seen in patients with a non-head-and-neck primary. In the multivariate analysis shown in Table ii, only patient age less than 80 years, a non-head-and-neck primary, and a higher \( T \) stage were found to be significant predictors of undergoing a slnb.

**CLND After a Positive SLNB**

Of the 746 patients who underwent slnb, 136 (18.2%) had a positive sentinel node. A clnd was performed in 82 (60.3%) of those 136 patients. Table iii shows the characteristics of patients who received a clnd. Although younger patients and patients with lower score on the Charlson comorbidity index tended to undergo clnd, no statistically significant associations were evident in univariate analysis. A multivariate analysis was not undertaken because of the small sample size.

**DISCUSSION**

In Ontario in 2013, the rate of slnb in intermediate-thickness melanoma was 65.5%, and in thick melanomas, it was 47.2%. The rate of clnd after the finding of a positive sentinel node was 60.3%. Those results show reasonable compliance with the asco/sso guidelines published in 2012\(^4\), although rates for slnb are a bit lower—and rates for clnd are certainly lower—than would have been expected.

The asco/sso guideline\(^8\) at that time recommended slnb for intermediate-thickness melanomas with a Breslow depth of 1–4 mm. Sentinel lymph node biopsy is considered a low-morbidity procedure, with an expected positivity rate of 20% in patients with an intermediate-thickness melanoma and clinically negative lymph nodes. Benefits include more accurate staging and prognostic information, and improved regional control\(^4\). The survival benefit of slnb based on the mslt-t\(^13\) subgroup analysis published in 2006 was not emphasized; the validity of the subgroup analysis showing a survival benefit has been questioned in the literature\(^5\)\(^6\)\(^7\). The asco/sso recommendations for slnb in patients with thick melanomas (Breslow depth > 4 mm) differed, with a “may be” rather than an “is” recommendation. That weakened recommendation was based on limited data in the relevant patient population and their poorer prognosis, which thus limits the potential for a survival benefit from the diagnosis and removal of metastatic regional lymph nodes. The guidelines from the U.S. National Comprehensive Cancer Network\(^11\) and Cancer Care Ontario\(^12\) recommend a discussion and an offer of slnb in any melanoma greater than 1 mm thickness. All three guidelines recommended a clnd after a positive sentinel node. This “simple” diagnostic test could thus lead to a more invasive procedure with the potential for significant long-term morbidity for individuals who test positive. The need for a standard of care requiring a clnd for a positive slnb was being investigated during that period by mslt-t\(^13\). In that study, patients with a positive slnb were randomized to clnd or no clnd, with a primary outcome of melanoma-specific survival. The questioning of a survival benefit for clnd, with its potential morbidity, likely accounts for gaps in compliance with guidelines for clnd after a positive slnb.

At 65.5%, our results for slnb in patients with intermediate or thick melanomas falls into the middle of previous population-level studies in the literature. Using U.S. Surveillance, Epidemiology, and End Results program data from 2001–2008, Wasif et al.\(^14\) found that 53% of patients with greater than stage ia melanomas and clinically negative nodes underwent slnb. However, Livingstone and colleagues\(^15\) reported an impressive rate of 87.8% using German population data from 2008. In Australia, where guidelines neither recommended nor discouraged slnb, the procedure was performed in 45% of patients with a melanoma of more
| Variable                                | Overall | Sentinel lymph node biopsy | \( \text{P Value}^{b} \) |
|-----------------------------------------|---------|---------------------------|--------------------------|
| Patients \((n)\)                       | 1973    | 746                       | 1227                     |
| Age (years)                             |         |                           |                          |
| Mean                                    | 63.8±16.3 | 60.9±14.9               | 65.5±16.9               | <0.001 |
| Median                                  | 65      | 62                        | 67                       |
| IQR                                     | 53–77   | 52–72                    | 54–80                   |
| Age group                               |         |                           |                          |
| <30 Years                               | 52      | 21 (40.4)                | 31 (59.6)               | <0.001 |
| 30–39 Years                             | 126     | 56 (44.4)                | 70 (55.6)               |
| 40–49 Years                             | 192     | 75 (39.1)                | 117 (60.9)              |
| 50–59 Years                             | 395     | 174 (44.1)               | 221 (55.9)              |
| 60–69 Years                             | 426     | 185 (43.4)               | 241 (56.6)              |
| 70–79 Years                             | 391     | 163 (41.7)               | 228 (58.3)              |
| ≥80 Years                               | 391     | 72 (18.4)                | 319 (81.6)              |
| Sex \([n (\%)]\)                       |         |                           |                          |
| Men                                     | 1078    | 416 (38.6)               | 662 (61.4)              | 0.433  |
| Women                                   | 895     | 330 (36.9)               | 565 (63.1)              |
| Income quintile \([n (\%)]\)           |         |                           |                          |
| Missing                                 |         |                            |                          |
| Missing                                 |         |                            |                          |
| ≤5                                     | 329     | 105 (35.8)               | 188 (64.2)              | <0.001 |
| 1                                      | 249     | 82 (32.9)                | 167 (67.1)              |
| 2                                      | 343     | 133 (38.8)               | 210 (61.2)              |
| 3                                      | 402     | 153 (38.1)               | 249 (61.9)              |
| 4                                      | 463     | 186 (38.9)               | 283 (61.1)              |
| 5                                      | 515     | 198 (38.4)               | 317 (61.6)              |
| Residence \([n (\%)]\)                |         |                           |                          |
| Rural                                   | 309     | 121 (39.2)               | 188 (60.8)              | 0.595  |
| Urban                                   | 1,664   | 625 (37.6)               | 1,039 (62.4)            |
| Score on the CCI \([n (\%)]\)          |         |                           |                          |
| 0                                      | 293     | 105 (35.8)               | 188 (64.2)              | <0.001 |
| 1                                      | 95      | 30 (31.6)                | 65 (68.4)               |
| 2                                      | 94      | 22 (23.4)                | 72 (76.6)               |
| ≥3                                     | 95      | 25 (26.3)                | 70 (73.7)               |
| No hospital admissions                  | 1396    | 564 (40.4)               | 832 (59.6)              |
| AJCC T stage \([n (\%)]\)              |         |                           |                          |
| T1                                     | 899     | 127 (14.1)               | 772 (85.9)              | <0.001 |
| T2                                     | 398     | 270 (67.8)               | 128 (32.2)              |
| T3                                     | 318     | 199 (62.6)               | 119 (37.4)              |
| T4                                     | 246     | 116 (47.2)               | 130 (52.8)              |
| TX or missing                           | 108     | 33 (30.6)                | 75 (69.4)               |
| Location of primary \([n (\%)]\)       |         |                           |                          |
| Head and neck                           | 397     | 82 (20.7)                | 315 (79.3)              | <0.001 |
| Trunk                                   | 654     | 265 (40.5)               | 389 (59.5)              |
| Upper extremity                         | 474     | ≤200                     | ≤280                    |
| Lower extremity                         | 425     | 200 (47.1)               | 225 (52.9)              |
| Skin NOS or genital                     | 23      | ≤5                       | ≤20                     |

\(^a\) Cells with nonspecific numbers reflect the ICES policy to protect individual identity by not reporting low numbers.

\(^b\) By chi-square test for categorical variables, and by one-way analysis of variance for continuous variables.

\(^c\) Based on a 5-year lookback.

IQR = 25%–75% interquartile range; CCI = Charlson comorbidity index; AJCC = American Joint Committee on Cancer; NOS = not otherwise specified.
than 0.75 mm Breslow depth in the years 2006–2007. Our rate of 47.2% SLNB for thick melanomas was lower than our rate for intermediate-thickness melanomas—likely reflecting the controversy concerning the benefits of SLNB in the former group. Wasif et al. showed a similar rate of SLNB (50.8%) in thick lesions. Consistent with our study, factors such as older age and a head-and-neck primary that predict noncompliance with SLNB are also found in the U.S. Surveillance, Epidemiology, and End Results program data analyzed by Wasif et al. and in the German study by Livingston. In the German study, noncompliance was also associated with micrometastatic nodal disease.

At 60.3%, compliance with CLND after a positive SLNB was similarly modest in our study and in other population-based studies, but lower than expected given that all the guidelines recommend a CLND after a positive SLNB. In the United States, rates of CLND after a positive sentinel node range from 50% to 69% in the U.S. Surveillance, Epidemiology, and End Results program data and in the U.S. National Cancer Database for 2004–2011. Despite high compliance with SLNB in the German study, whose patients were treated in 2008, the rate of CLND for positive nodes was surprisingly modest at 60%. The Australian study showed that CLND was performed in 69% of patients with a positive SLNB. Ontario’s universal health care might account for the lack of an effect of socioeconomic status on procedure rates as found in the study by Bilmoria et al. in the United States.

Our study has a number of important strengths, including the large cohort size and the acquisition of multi-institutional and population-based information that make the results more generalizable. Limitations include the use of administrative data that might not be accurate or might be incomplete. Additionally, more granular data concerning the primary lesion (such as tumour ulceration) were not readily available. Provider and regional variation were not explored because of concerns about biases that could exist because of referral patterns—a concern that could not be eliminated using the administrative data.

The ASCO/SSO recommendations for SLNB and CLND were updated in 2018, making the present results somewhat obsolete. Based on the findings from MSLT-II and evidence of a survival benefit with adjuvant immunotherapies in patients having node-positive melanoma, recommendations for SLNB are more favourable for thin melanomas with ulceration and for T1b (0.8–1.0 mm) and T4 (>4.0 mm) lesions. In most cases, given the equivalent survival in the resected and observation groups in MSLT-II, CLND is no longer recommended. Based on the lower-than-expected compliance with the previous guideline observed in that study, timely review of current practice patterns in relation to the new guideline is warranted.

**CONCLUSIONS**

We examined rates and predictors of receipt of SLNB in patients with melanoma living in the province of Ontario. We found lower than expected but moderate compliance with the guidelines recommending SLNB and subsequent CLND for positive nodes, consistent with other published studies.

**ACKNOWLEDGMENTS**

Support for SL’s participation in the ICES Western Faculty Scholars Program came from the Department of Surgery and Division of General Surgery, Schulich School of Medicine and Dentistry, Western University, London, ON.
### TABLE III  Characteristics of the study patients by use of completion lymph node dissection (CLND) after positive sentinel lymph node biopsy (SLNB)\(a\)

| Characteristic                  | Underwent SLNB | Outcome: CLND | \(p\) Value\(b\) |
|---------------------------------|----------------|---------------|------------------|
| Patients (n)                    | 136            | 82            | 54               |
| Age (years)                     |                |               |                  |
| Mean 59.0±14.20                 |                | 57.3±14.8     | 61.6±12.9        | 0.085 |
| Median 60                      |                | 59            | 62               |
| IQR 51–70                      |                | 45–66         | 54–70            |
| Age group [n (%)]               |                |               |                  |
| <40 Years                       | 16             | ≤15           | ≤5               | 0.155 |
| 40–49 Years                     | 16             | 9 (56.3)      | 7 (43.8)         |
| 50–59 Years                     | 34             | 19 (55.9)     | 15 (44.1)        |
| 60–69 Years                     | 35             | 23 (65.7)     | 12 (34.3)        |
| 70–79 Years                     | 24             | 11 (45.8)     | 13 (54.2)        |
| ≥80 Years                       | 11             | ≤10           | ≤5               |
| Sex [n (%)]                     |                |               |                  |
| Men 86                          |                | 54 (62.8)     | 32 (37.2)        | 0.435 |
| Women 50                        |                | 28 (56.0)     | 22 (44.0)        |
| Income quintile                 |                |               |                  |
| Missing 0                       | 0              | 0             | 0                | 0.475 |
| 1                               | 20             | ≤15           | ≤5               |
| 2                               | 21             | ≤15           | ≤10              |
| 3                               | 30             | 18 (60.0)     | 12 (40.0)        |
| 4                               | 28             | 16 (57.1)     | 12 (42.9)        |
| 5                               | 37             | 19 (51.4)     | 18 (48.6)        |
| Residence                       |                |               |                  |
| Rural 13                        |                | ≤10           | ≤5               | 0.489 |
| Score on the CCI\(c\)           |                |               |                  |
| 0                               | 17             | 10 (58.8)     | 7 (41.2)         | 0.128 |
| ≥1                              | 16             | 6 (37.5)      | 10 (62.5)        |
| No hospital admissions 103      |                | 66 (64.1)     | 37 (35.9)        |
| AJCC T stage                    |                |               |                  |
| T1, TX, or missing              | 9              | ≤10           | ≤5               | 0.92  |
| T2                              | 30             | ≤20           | ≤15              |
| T3                              | 57             | 34 (59.6)     | 23 (40.4)        |
| T4                              | 40             | 25 (62.5)     | 15 (37.5)        |
| Location of primary             |                |               |                  |
| Head and neck 13                |                | 7 (53.8)      | 6 (46.2)         | 0.965 |
| Trunk 53                        |                | 32 (60.4)     | 21 (39.6)        |
| Upper extremity 28              |                | 17 (60.7)     | 11 (39.3)        |
| Lower extremity 42              |                | 26 (61.9)     | 16 (38.1)        |
| Skin NOS or genital             | 0              | 0             | 0                |

\(a\) Cells with nonspecific numbers reflect the ICES policy to protect individual identity by not reporting low numbers.

\(b\) By chi-square test for categorical variables, and by one-way analysis of variance for continuous variables.

\(c\) Based on a 5-year lookback.

IQR = 25%–75% interquartile range; CCI = Charlson comorbidity index; AJCC = American Joint Committee on Cancer; NOS = not otherwise specified.
We thank Dr. Krista Bray Jenkyn for her early contributions to this work.

This study was supported by iccs Western, which is funded by an annual grant from the Ontario Ministry of Health and Long-Term Care. Core funding for iccs Western is provided by the Academic Medical Organization of Southwestern Ontario, the Schulich School of Medicine and Dentistry, Western University, and the Lawson Health Research Institute. The opinions, results, and conclusions reported in this article are those of the authors and are independent from the funding sources. No endorsement by the funding sources is intended or should be inferred. Parts of this material are based on data and information compiled and provided by the Canadian Institute for Health Information (cihi); however, the analyses, conclusions, opinions, and statements expressed herein are those of the authors and not necessarily those of cihi.

CONFLICT OF INTEREST DISCLOSURES
We have read and understood Current Oncology’s policy on disclosing conflicts of interest, and we declare that we have none.

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