The American Journal of Surgery 217 (2019) 527–531

Contents lists available at ScienceDirect

The American Journal of Surgery

journal homepage: www.americanjournalofsurgery.com

Quality improvement in melanoma care: Multidisciplinary quality program development and comparison of care before and after implementation

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ARTICLE INFO

Article history:
Received 18 July 2018
Received in revised form
11 October 2018
Accepted 13 October 2018

Keywords:
General surgery
Surgical oncology
Dermatology
Skin cancer
Melanoma
Quality improvement
Database
Melanoma guidelines

ABSTRACT

Introduction: Adherence to guideline-based care for melanoma remains suboptimal. This study describes the development of a quality monitoring program and compares the quality of care before and after its implementation.

Methods: Thirty quality metrics were adopted. An abstraction tool, manual and electronic database were developed. Metrics were analyzed from 1/1/2008-8/31/2013 (Group A) and compared to melanoma care from 9/1/2013-12/31/2017 (Group B).

Results: A total of 311 patients were treated from 2008 to 2017. Demographic data were similar between the groups.

21.7% of patients in Group A had clinical stage (TNM) documented before surgery compared to 100% in Group B. 86.9% of patients in Group A had surgical margins documented in the operative report compared to 100% of Group B. Appropriate surgical margins were obtained in 85.7% of Group A compared to 99.5% in Group B. Pathology reporting of margin status, satellitosis, regression and mitotic rates improved from ~60% Group A to >92% in Group B. Multidisciplinary process and structural metrics were unchanged.

Conclusions: A comprehensive melanoma quality program has produced significantly improved guideline-based multidisciplinary care.

Introduction

Deviation from guideline based medical care is well documented and the treatment of malignant melanoma is no exception.[1,2] Previous reports on melanoma care have identified underutilization of sentinel node biopsy, inadequate lymph node retrieval following lymphadenectomy, and insufficient surgical margins.[2–5] Despite identification of these shortcomings, and the publication of practice based guidelines, melanoma care remains suboptimal.[1–5]

Notable advancements in healthcare quality have been accomplished through collaboration and critical outcomes assessment.[6] Thus far, there has been no formal endorsement of broad quality measures by oncology, dermatology, or surgical societies. Kang and Wong hypothesized that this lack of guideline based care in melanoma is due to physician bias, inadequate medical knowledge, and lack of trust in the system.[7] Yet, a formal set of melanoma quality indicators was introduced in the United States in 2009.[8] To date, there has been no report on the implementation of these measures, nor any institutional reports on compliance or outcome improvement.

This study assesses the quality of melanoma care provided in a community teaching hospital through development of a comprehensive melanoma quality program. In doing so, the original quality measures proposed in 2009 were adopted, with the addition of four contemporary quality measures.[8] We report on the methods of

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https://doi.org/10.1016/j.amjsurg.2018.10.025
0002-9610/

implementing this quality assessment program for melanoma and substantiate findings through comparison with previously published data as well as the quality of care during the 4 years prior to program implementation.

Methods

The study was submitted to the institutional IRB for approval and designated a quality improvement project. Twenty-six published quality indicators endorsed by expert panel members were adopted.[8] Four additional quality measures were implemented based on advancements in melanoma care since 2009. A data abstraction tool, including demographic data and management guidelines, was developed and refined. A data abstraction manual was created to define quality measures and facilitate abstractor consistency. Both the abstraction tool and manual were refined through a practice-based approach with monthly reviews to ensure appropriate abstraction. Changes were made and tracked throughout the process to ensure consistency with data abstraction and definitions of specific data points. A MIDAS electronic database was constructed. Data abstraction was performed by trained abstractors within 3 months of patient care initiation over a four year period from September 1, 2013 to December 31, 2017 (Group B). Outcome reports were reviewed on a quarterly basis to assess quality of care metrics and multi-disciplinary management. This was then compared to a retrospective review of all patients with melanoma treated at the institution from January 1, 2008 to August 31, 2013 (Group A).

Patients were included if they were diagnosed with new or recurrent melanoma and underwent biopsy, surgery, or any treatment for recent diagnosis of melanoma. Additionally, patients were included if they underwent shave, punch, core needle or excisional biopsy, fine needle aspiration, wide local excision (WLE), lymph node biopsy, sentinel lymph node biopsy (SLNB), or lymph node dissection (LND) at initial presentation. Patients with disease recurrence were included if they underwent surgical therapy (metastectomy, lymphadenectomy) biologic therapy (interferon, immunotherapy) or chemotherapy even if initial surgical treatment was performed elsewhere. Final pathology was required to demonstrate melanoma in situ or invasive melanoma.

Patients were excluded if they had no history of biopsy nor treatment for melanoma at the institution. Patients with pathology not conclusive for melanoma were excluded. Patients were also excluded if diagnosed with melanoma but were undergoing treatment for a different malignancy or deemed ineligible or too ill to initiate any treatment for melanoma.

Statistical analysis was undertaken using STATA software with both Pearson's Chi-Square and Fisher's exact analysis. Statistical significant was defined as those data with p-values <0.05.

Results

311 patients with melanoma were treated over the 9 year study period. 27 patients were reviewed retrospectively in Group A from January 1, 2008 to August 31, 2013. Treatment and outcomes were compared to 284 patients treated within the program September 1, 2013 to December 31, 2017 (Group B). Mean age of 60.3 years (range: 18–92 years). 172; 55.3% patients were male. The majority of patients ($n = 283$, 90.9%) had an initial diagnosis of melanoma. The anatomic location for 283 initial diagnoses included head and neck ($n = 55$, 19.4%), trunk ($n = 121$, 42.8%), extremity ($n = 101$, 35.7%) and unknown primary ($n = 6$, 2.1%).

Throughout the study period a total of 229 patients underwent initial resection of the primary lesion with or without SLNB. 13 patients underwent initial resection of primary lesion with initial or subsequent completion lymph node dissection (CLND). All surgeons performing SLNB or CLND during the study period were certified by the American Board of Surgery or equivalent.

Clinical stage was documented prior to surgical intervention in only 5 (21.7%) patients in Group A compared to 219 (100%) in Group B ($p = 0.001$) (Table 1). A discussion regarding performing SLNB along with WLE was documented in all patients presenting with clinical stage IB or II disease. Among all 219 patients (both study groups) who presented with clinical stage 0, I, or IIA disease, no patient underwent initial radiographic cross-sectional imaging (CT or MRI or PET) unless specifically indicated by patient symptoms or clinical findings.

For WLE of the primary tumor, surgeons documented the measured surgical margin of excision in the operative report in 86.9% for Group A compared to 219 (100%) in Group B ($p = 0.249$) The stage specific guideline-based surgical margin was obtained in 21 (85.7%) patients in Group A compared to 218 (99.5%) in Group B ($p = 0.199$). See Table 1 for additional surgical margin information.

A total of 165 patients (both groups) underwent SLNB. All 136 patients (both groups) with stage IB or II disease underwent SLNB. SLNB performance before and after program implementation was evaluated with stage-specific outcomes (See Table 1). Overall, the mean number of SLNs removed per patient was 2.1 (range 1–7 nodes). Lymph node dissection performance did not differ between groups.

Final histologic margins were clear of melanoma and/or melanoma in situ in 22 (91.7%) in Group A compared to 224 (97.4%) in Group B ($p = 0.076$). Serial sectioning of lymph nodes was completed in only 9 (60%) Group A patients compared to 143 (98.6%) in Group B ($p = 0.292$). The number of SLN examined and identified with/without metastasis was documented in all (100%) pathology reports for both groups. Additionally, the number of non-SLN with/without metastasis was documented in all 18 CLND pathology reports in both groups.

From 2008 to 2013 pathology report content was not standardized. With implementation of the quality program tumor characteristics were reported in a standardized format per recommendations of the College of American Pathologists. In an effort to provide summary synoptic reporting, our pathology department agreed to incorporate features of the original biopsy, particularly if the specimen from the WLE demonstrated no residual disease or melanoma of a lesser Breslow depth than the original biopsy. This was adopted in 2014, after initiation of the quality monitoring program, resulting in some missing elements in approximately 7–10% of pathology reports; the vast majority from 2013. Even with this discrepancy, process improvement resulted in >92% compliance with pathology guidelines for Group B compared to Group A which demonstrated <60% compliance (see Table 2).

Consultation with medical oncology and a discussion of adjuvant therapy was conducted with 6 patients (75%) in Group A with stage III, recurrent, or metastatic disease compared to 60 patients (96.8%) in Group B ($p = 0.201$). Potential clinical trial participation, BRAF mutation testing performance, LDH performance and stage specific follow-up discussion were also improved in Group B when compared to Group A although not statistically significant.

Discussion

Quality assessment of cancer care in the United States is shifting away from a limited focus on patient volumes and single endpoint analysis (i.e. mortality) to more comprehensive assessment of quality based on evidence-based care processes and disease-specific outcomes.[6] According to Porter, factors limiting progress in multi-endpoint analysis of care are hypothesized to be a lack of adoption of consensus guidelines, limited clinical detail in

Table 1
Surgical quality metrics.

	Group A Metric Compliance	Group B Metric Compliance	p-Value
Clinical Stage (TNM) documented prior to surgical intervention	5, 21.7%	219, 100%	0.001
Surgical margin documented in operative report	20, 86.9%	219, 100%	0.249
SLNB discussed for disease stage IB or II	1, 100%	135, 100%	1.00
Initial appropriate radiologic utilization for Stage 0, I, IIa disease	15, 100%	204, 100%	1.00
Surgical Excision with requisite surgical margins			
Melanoma in situ: Surgical margins $\geq$ 5 mm	2, 66.6%	23, 100%	0.181
Melanoma $\leq$ 1 mm Breslow Thickness: Surgical margins $\geq$ 1 cm	7, 100%	108, 100%	1.00
Melanoma 1–2 mm Breslow Thickness: Surgical margins 1–2 cm	4, 80%	59, 100%	0.103
Melanoma $\geq$ 2 mm Breslow Thickness: Surgical margins 2–3 cm	5, 83.3%	22, 95.7%	0.042
Digit Melanoma: Proximal Joint	NA	6, 100%	NA
Total	21, 85.7%	218, 99.5%	0.199
Sentinel Lymph Node Biopsy Quality Measures			
Lymphoscintigraphy performed	15, 100%	149, 99.3%	1.00
Sentinel lymph node identified	15, 100%	145, 96.7%	1.00
Sentinel lymph node NOT sent for frozen section	15, 100%	144, 99.3%	1.00
No SLN biopsy if biopsy proven palpable nodal disease	NA	6, 100%	NA
Sentinel Lymph Node Biopsy Appropriateness			
SLNB performed in stage Ib	NA	96, 100%	NA
SLNB performed in stage IIa, IIb, IIc	NA	25, 100%	NA

administrative databases, and the additional costs required to measure and report on disease-specific outcomes.[6] Kang and Wong recently expanded on factors contributing to failure to adopt more broad scale clinical guidelines in the management of melanoma.[7] A lack of trackable consensus guidelines, limited clinical data and absence of disease specific outcomes within administrative databases were all felt to be contributing factors in limiting quality assessment of melanoma care.

Despite the above mentioned limitations, other surgical societies have been successful and provide evidence that a more nuanced assessment of quality of cancer care is feasible. The Society of Thoracic Surgeons has maintained a detailed clinical database since 1989, allowing for detailed assessment of surgical outcomes as well as quality of care for patients undergoing thoracic surgical procedures. This has resulted in the ability to assess patient care, outcomes, and develop risk stratification and mortality guidelines in the management of malignant and non-malignant thoracic disease. Similarly, Northern New England Cardiovascular Disease Study Group (NNECDSG) has facilitated a detailed assessment of regional cardiovascular care since 1987. These efforts have contributed to substantial improvements in outcomes including decreased mortality associated with CABG and other subspecialty cardiothoracic procedures. To our knowledge there has been no regional nor professional society collaborative to assess quality of surgery or other aspects of cancer treatment for melanoma patients.

Bilimoria et al. published consensus multi-disciplinary quality indicators in 2009, offering a new platform to measure and compare the quality of melanoma care.[8] These indicators included structural and process measures for surgery, radiology, pathology, as well as medical oncology. This study is the first to report on a process to formally implement these measures into a program of measurement, analyses, reporting, and quality improvement. Our strategy for accomplishing this task was to develop an instrument and data dictionary that adequately captured all required metrics, despite the tremendous variation in patients' clinical presentation.

Melanoma surgical outcomes reports traditionally have been limited to measures such as appropriate surgical margins and utilization of SLNB in relation to clinical stage. The current program incorporated additional process measures of surgeon performance,

Table 2
Pathology quality metrics.

	Group A Metric Compliance	Group B Metric Compliance	p-Value
Clear histological margin documented	22, 91.7%	224, 97.4%	0.076
Serial sectioning completed on sentinel lymph node biopsy	9, 60%	143, 98.6%	0.292
Pathology report documented number of sentinel lymph node examined with/without metastases	15, 100%	145, 100%	1.00
Pathology report documented number of non-sentinel lymph nodes with/without metastasis	1, 100%	17, 100%	1.00
Documentation of tumor characteristics for invasive melanoma			
Anatomic Location of the Lesion[a]	26, 100%	248, 100%	0.713
Breslow Thickness	19, 90.5%	199, 93.4%	0.009
Clark Level	19, 90.5%	195, 92.0%	0.004
Histologic Ulceration	19, 90.5%	198, 93.8%	0.017
Peripheral/Radial Margin status	14, 66.7%	213, 99.5%	0.453
Deep Margin Status	14, 66.7%	207, 98.1%	0.546
Satellitosis	12,57.1%	196, 92.9%	0.421
Regression	14, 66.7%	194, 91.5%	0.78
Mitotic Rate	11, 52.4%	196, 92.9%	0.145

[a] Anatomic location also included patients with melanoma in-situ and metastectomies.

offering a more comprehensive assessment of surgical quality. Bilimoria previously identified less than 50% of clinical stage Ib/II melanoma patients underwent SLNB in their first course of treatment, even though SLNB is a cornerstone of melanoma staging in these patients. As few as 34.1% of new patients had no pathologic nodal assessment completed.[9] This contrasts significantly with our institution for which a discussion regarding performance of SLNB was documented in 99% of stage appropriate patients. Prior studies also documented a CLND in as few as 50% of patients with a positive SLNB with only two thirds of such lymphadenectomies resulting is assessment of the recommended number of lymph nodes.[10] Quality assessment of surgeon performance in this study included documentation of requisite surgical margins based on preoperative clinical staging, offering insight into surgeons' judgment and guideline awareness. A lack of consistency in operative reports can lead to challenges in assessing surgical margin appropriateness. Completeness of pathologic staging is essential to assessing appropriateness of patient surveillance. This program consistently maintains quality metrics >90% in these categories and is substantiated through comparison to the suboptimal findings in the 4 years prior to its implementation (See Table 1).

Clinical management of malignant disease depends on the accuracy and consistency of pathology processes and reporting. It has been reported that 12% of SLNB metastasis will be missed if only hematoxylin and eosin staining are used in absence of immunohistochemistry staining for markers such as like S-100, HMB-45, and MART-1.[11] The current program has resulted in >92% adherence to pathology quality metrics in Group B (Table 2), a significant improvement when compared to previous data. Much of this improvement can be attributed to review of available institutional outcomes, with revision of previous pathology sectioning protocols as well as revisions in melanoma reporting expectations. These changes were achieved through meetings of program leaders interested in quality improvement.

The present study has several limitations. The design and restricted timeframe of this project limits the ability to assess the impact of achieving these specific outcomes in melanoma care to traditional cancer outcomes such as local recurrence, disease free survival, and death. The number of patients in Group A is quite limited and involves several surgeons performing low volume melanoma surgery, and the data from time period B while also involving several surgeons, does have a significant representation of a high volume melanoma surgeon. The large increase in patient volume for Group B after 2013 does coincide with the arrival of a surgical oncologist at our institution with a clinical interest in melanoma care. Nevertheless, we feel the improvements in metrics were partially attributable to the quality program. With the continuous cycle of outcomes assessment, and subsequent meetings with clinical leaders in radiology and pathology as well as medical oncology, outcomes improved across multiple disciplines of care. It should also be noted that the results of this study were completed prior to the publication of the MSLT-II Trial, and thus, CLND may have a limited role in SLN positive patients as a quality metric moving forward.[12]

Conclusions

A comprehensive melanoma quality assessment program has been developed and successfully implemented at our institution. This system, including a functional electronic component, facilitates ease of review and comparison to published quality metrics, allowing assessment of quality of melanoma care. Comparison of contemporary data to that rendered in the same institution, prior to its development identifies a significant improvement in guideline based care. Expansion of this database will be required in order to uncover it's impact on disease recurrence, recurrence free survival and death.

Conflicts of interest

The authors have no conflicts of interest to disclose.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.amjsurg.2018.10.025.

Appendix #1. Melanoma care quality metrics

Surgical Metrics (21 indicators)
If surgeon performs sentinel lymph node biopsy (SLNB) or lymph node dissection (LND) for melanoma, then the surgeon must be certified by the American Board of Surgery of equivalent board or international association.
*Prior to surgical resection clinical stage (TNM staging) should be documented by the surgeon.**
If patient has melanoma in situ, then the surgical excision margins must be at least 5 mm (or specific anatomic or cosmetic factors that limit margin distance should be noted).
If a patient has melanoma, then the surgeon must document the measured surgical margin in the operative note.
If a patient has a melanoma $\leq$ 1 mm thick, then the surgical excision margins must be 1 cm (or specific anatomic or cosmetic factors that limit margin distance should be noted).
If a patient has a melanoma 1–2 mm thick, then the surgical excision margins must be 1–2 cm (or specific anatomic or cosmetic factors that limit margin distance should be noted).
If a patient has a melanoma $\geq$ 2 mm thick, then the surgical excision margins must be 2–3 cm (or specific anatomic or cosmetic factors that limit margin distance should be noted).
If a patient is to undergo a SLNB, then lymphoscintigraphy must be performed to identify the draining nodal basin(s).
If a patient is to undergo a SLNB, then the sentinel lymph nodes must be sent for permanent sectioning only (no frozen sections), unless a reason is documented.
If a patient has a stage IB or II melanoma, then performance of a SLNB must be discussed with a patient.
*If a SLNB is performed, then the surgeon should identify the sentinel lymph node (defined as a hot node, or blue node or palpable node) in the operating room, and this should be confirmed as a lymph node on histologic evaluation.**
If a patient has clinically apparent/palpable lymphadenopathy, then a lymph node dissection must not be performed without an antecedent histologic diagnosis.
If a patient undergoes a cervical lymph node dissection or completion lymph node dissection (CLND), then at least 15 regional lymph nodes must be resected and pathologically examined.
If a patient undergoes an axillary lymph node dissection or CLND, then at least 10 regional lymph nodes must be resected and pathologically examined.
If a patient undergoes an inguinal lymph node dissection or CLND, then at least 5 regional nodes must be resected and pathologically examined.
If a patient has clinically palpable nodal disease of the inguinofemoral nodes, then a pelvic computed tomography (CT) or Positron Emission Tomography (PET) must be obtained to rule out pelvic lymphadenopathy.

(*continued*)

Surgical Metrics (21 indicators)
If a patient has stages 0, I, or IIA melanoma, then an abdominal CT or abdominal magnetic resonance imaging (MRI), pelvic CT/MRI, or PET scan are NOT indicated unless in response to specific signs or symptoms.
If a patient with melanoma has biopsy-proven or palpable nodal disease and no evidence of distant metastases, then the patient must undergo a CLND, or documentation indicating the patient's severe comorbidities or patient's declining lymph node dissection.
If a patient has a metastatic lymph node detected on SLNB, then a CLND must be performed except in the context of a clinical trial or if the patient has severe comorbidities.
If a patient with melanoma has biopsy-proven, palpable nodal disease, then the patient should not undergo SLNB.
*If a patient has clinically palpable nodal disease, then a PET scan should be performed prior to CLND to rule out distant metastases.**
Pathology Metrics (4 indicators)
If a patient has a melanoma, then a clear histological margin must be documented following final excision.
If a patient undergoes a sentinel lymph node biopsy, then the sentinel lymph nodes must be examined with serial sectioning, Hematoxylin and Eosin (H&E) staining and with immunohistochemistry (IHC) if the H&E analysis is negative or equivocal (i.e., S-100, HMB-45, and MART-1).
If a patient has an invasive melanoma, then the pathology report must document Breslow thickness, Clark level, histologic ulceration, peripheral/radial and deep margin statuses, satellitosis, anatomic location of the lesion, regression, and mitotic rate.
If a patient undergoes a sentinel lymph node biopsy or lymph node dissection for melanoma, then the pathology report must document the number of lymph nodes examined and the number of lymph nodes found to contain metastases.
Advanced Disease Metrics (5 indicators)
If a patient has a resected primary melanoma metastatic to regional lymph nodes or resected distant sites, then the patient must have a documented discussion regarding adjuvant therapy.
If a patient is newly diagnosed with stage IV melanoma, then a serum lactate dehydrogenase (LDH) level must be measured.
If a patient is treated for melanoma, then stage-specific follow-up, including future skin exams, should be discussed and documented.
If a patient is treated for stage IV melanoma then the availability and/or potential treatment under a clinical trial should be discussed and documented.
*If a patient with melanoma has documented nodal metastases or distant metastases then BRAF testing should be completed on the pathologic specimen.**

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