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Wound Complications after Inguinal Lymph Node Dissection for Melanoma: Is ACS NSQIP Adequate?

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Abstract

Background—In the treatment of melanoma, inguinal lymph node dissection (ILND) is the standard of care for palpable or biopsy-proven lymph node metastases. Wound complications occur frequently after ILND. In the current study, the multicenter American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP) was utilized to examine the frequency and predictors of wound complications after ILND.

Methods—Patients with cutaneous melanoma who underwent superficial and superficial with deep ILND from 2005-2010 were selected from the ACS NSQIP database. Standard ACS NSQIP 30-day outcome variables for wound occurrences—superficial surgical site infection (SSI), deep SSI, organ space SSI, and disruption—were defined as wound complications.

Results—Of 281 total patients, only 14 % of patients had wound complications, a rate much lower than those reported in previous single institution studies. In a multivariable model, superficial with deep ILND, obesity, and diabetes were significantly associated with wound complications. There was no difference in the rate of reoperation in patients with and without wound complications.

Conclusions—ACS NSQIP appears to markedly underreport the actual incidence of wound complications after ILND. This may reflect the program's narrow definition of wound occurrences, which does not include seroma, hematoma, lymph leak, and skin necrosis. Future iterations of the ACS NSQIP for Oncology and procedure-specific modules should expand the definition of wound occurrences to incorporate these clinically relevant complications.

More than 800,000 people in the United States have cutaneous melanoma.¹ For patients with palpable or biopsy-proven lymph node metastases, inguinal lymph node dissection (ILND) is the standard of care. Wound complications after ILND in the treatment of melanoma are common, with rates ranging from 64–77% in prospective studies.^{2–4} These studies have utilized a variety of definitions of wound complications, including not only surgical site infections but other complications, such as seroma, hematoma, skin necrosis, and delayed healing. In addition to using inconsistent definitions of the primary outcome, these prior studies have been limited by small sample sizes and single-institution design. Therefore, our objective was to determine the contemporary rate and predictors of wound complications after inguinal lymph node dissection for melanoma in a large multi-institutional cohort using

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precisely defined variables. The hypothesis was that wound complications after ILND for cutaneous melanoma are frequent and associated with both patient and procedure-related factors.

METHODS

Data and Patients

The source of data for the study was the Participant Use Data File (PUF) of the American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP). ACS NSQIP collects prospective data from participating medical centers for the purpose of surgical quality improvement. At each site, a surgical clinical reviewer utilizes medical record review and patient interview to record information on precisely defined variables describing patient demographics, comorbidities, preoperative laboratory values, operative variables, and 30-day postoperative outcomes, including 21 complications, reoperation, length of stay, and mortality. After removing patient identifiers, ACS NSQIP makes these data available to participating sites in the form of the PUF for quality improvement and research purposes. Information about the ACS NSQIP, training and oversight of personnel, sampling and data collection methodology, and variable definitions are available online.⁵

Using the ACS NSQIP PUF, all patients with a diagnosis of melanoma (International Classification of Diseases, 9th Edition, Clinical Modification [ICD-9-CM] codes 172–172.9) who underwent superficial or superficial with deep inguinal lymph node dissection (Current Procedural Terminology [CPT] codes 38760 and 38765) from 2005–2010 were identified. As the primary outcome was postoperative wound complication, 25 patients were excluded due to preexisting infected or open wounds, 1 patient for preoperative sepsis, and 4 who underwent procedures with "contaminated" or "dirty" wound classifications.

Outcomes

The primary outcome was wound complication, which was defined as the presence of one or more of the following ACS NSQIP "wound occurrence" variables: superficial surgical site infection (SSI), deep SSI, organ space infection, and wound disruption. ACS NSQIP uses the Centers for Disease Control and Prevention (CDC) definitions of wound infection for superficial SSI, deep SSI, and organ space infection.⁶ The CDC definition of wound infection requires documentation of at least one of the following: purulent drainage, abscess, positive cultures, signs of infection and opening of the wound, and/or a diagnosis by the attending physician or surgeon. In the absence of one of the above, specific criteria, documentation of signs of wound infection, such as erythema or induration, or treatment with antibiotics is insufficient to meet the standard of the CDC definition of wound infection. Wound disruption is defined by ACS NSQIP as separation of the layers of a surgical wound, which may be partial or complete, with disruption of the fascia. Importantly, current ACS NSQIP wound occurrence variables do not capture hematomas, seromas, lymph leak requiring prolonged tube drainage, skin necrosis, or delayed wound healing. Secondary outcomes included 30-day mortality and reoperation.

Variables

Potential explanatory and control variables used in the analysis included patient demographics, comorbidities, preoperative laboratory values, and operative variables, as shown in Table 1. The variable list was examined and comorbidities with a frequency of less than 2 % in the overall sample were removed from further analysis. Additionally, the laboratory variables for white blood cell count and albumin were removed from further analysis because at least 15 % of the values were missing.

Statistical Analysis

Summary statistics were generated to describe patient demographics, comorbidities, preoperative laboratory values, and operative characteristics. Univariate statistical tests were used to describe the frequencies of patient characteristics: χ^2 for categorical variables, and Wilcoxon rank-sum and *t* tests for continuous variables. Multivariate logistic regression analysis was performed on variables with a *p* value of 0.05 or less on the univariate analysis to calculate adjusted odds ratios, 95 % confidence intervals, and adjusted predicted probabilities for wound complications after ILND. All statistical analyses were performed using Statistical Package for the Social Sciences (SPSS) software, version 19.

RESULTS

Patient Characteristics

A total of 281 patients underwent ILND for melanoma and otherwise met the inclusion criteria for the study. Patient characteristics are shown in Table 1.

Frequency of Wound Complications and Univariate Analysis of Risk Factors

Forty patients (14.2 %) had a wound complication according to ACS NSQIP definitions. These 40 patients had a total of 45 wound complications: 33 superficial SSI, 4 deep SSI, 1 organ space infection, and 7 wound disruptions. Only one patient died within 30 days after surgery, and that individual did not have a recorded wound complication. The frequency of 30-day reoperation in patients who had a wound complication was 12.5 % compared with 5.8 % in those who did not have a recorded wound complication, but this difference was not statistically significant (p = 0.16).

Univariate analyses were performed to identify risk factors associated with wound complication after ILND; the results are summarized in Table 1. Obesity, diabetes, and having a more extensive ILND were all associated with higher rates of wound complication.

Multivariate Analysis of Predictors of Wound Complications

To determine predictors of wound complication after ILND for melanoma, a multivariable model was created, which included body mass index class, diabetes, and extent of inguinal dissection. The results of the multivariate analysis are shown in Table 2. Obesity, diabetes, and extent of ILND were all significantly associated with the outcome.

DISCUSSION

This is the largest reported study to examine patient complications after inguinal lymph node dissection for melanoma and is the first with a multi-institutional design. In this series of patients, only one of seven, or 14.2 % of patients who had an inguinal lymph node dissection for melanoma developed a wound complication according to ACS NSQIP definitions. Three factors were found to predict wound complications after ILND for cutaneous melanoma: obesity, diabetes, and undergoing a more extensive lymphadenectomy.

Compared with single-institution studies with wound complication rates of up to 77 %, wound complications after ILND were significantly lower in this analysis of ACS NSQIP data.² There were two major differences between the outcomes and variables used in the current study and the previous single-institution studies, which may account for this discrepancy: (1) which wound occurrences were included in the primary outcome of "wound complication," and (2) how wound infection was defined. Previous studies have used expanded definitions of wound complications that included additional variables, such as seromas, hematomas, wound breakdown/skin necrosis, and delayed healing, whereas ACS

NSQIP limits wound occurrences to surgical site infections and wound disruption.^{2,4,7–13} In addition, whereas previous studies on wound complications include any use of therapeutic antibiotics in the criteria for defining wound infections, ACS NSQIP uses the strict CDC definitions for surgical-site infections, which do not include the administration of therapeutic antibiotics alone as a definition of wound infection.^{2–4,6–11,13,14}

A review of the literature identified seven previous studies that reported risk factors for development of wound complications after ILND for melanoma (Table 3). The current study found a BMI of 30 or greater to be associated significantly with wound complications after ILND for cutaneous melanoma. This finding is consistent with results from other studies.

The current study also found a significant relationship between diabetes and the development of wound complications and is the first study to demonstrate a positive association between these two factors in patients undergoing ILND for melanoma. The study performed by Chang et al. is the only other study that examined this relationship.² The lack of a significant association between diabetes and wound complications in their study was likely related to the small sample (n = 53, only 6 of whom had diabetes). Additionally, the current study was the first to find that patients who underwent a combined superficial and deep ILND had an increased risk of developing wound complications compared with patients who only underwent a superficial ILND. The three previous studies that examined this relationship and found no association also were likely limited by small sample size.^{2,9,11}

Limitations

The most significant limitation to our study was the failure of ACS NSQIP to capture all patients with clinically relevant wound complications. Whereas the current study was able to link obesity, diabetes, and undergoing a superficial and deep lymphadenectomy with wound complications as defined by ACS NSQIP, it is unknown whether these risk factors would still be significant, or if additional risk factors would be identified, if an expanded range of wound complications were adequately recorded.

ACS NSQIP includes a large number of precisely defined preoperative and postoperative variables. However, because it is part of a national quality improvement initiative, it does not currently capture clinical data specific to melanoma surgery that may contribute to wound complications, including oncologic information, such as stage, method of presentation (sentinel lymph node biopsy-positive versus palpable lymphadenopathy), and number of involved lymph nodes; operative variables, including the type of incision and approach; and postoperative care factors, including the duration of drain use. Additional limits of ACS NSQIP include the lack of data regarding patient socioeconomic status, surgeon variables, such as fellowship training, specialty within general surgery, and case volume, as well as hospital size, procedure volume, and certification as a cancer center. Finally, although the current study established diabetes as a significant risk factor for the development of wound complications, ACS NSQIP does not currently provide perioperative blood glucose or hemoglobin A1c levels. This limits the ability to evaluate the association of wound complication with peri-operative hyperglycemia or long-term glycemic control.

CONCLUSIONS

This large, multi-institutional, prospective study on wound complications after inguinal lymph node dissection for melanoma has two important implications. First, this study has identified three significant predictors of wound complications after this procedure—diabetes mellitus, obesity, and increased extent of nodal dissection—and this information may be useful both for preoperative patient counseling and also to enhance postoperative monitoring of these high-risk patients to recognize and treat wound complications early in their course.

Second, the lower-than-expected overall rate of wound complications suggests that additions and modifications to the current list of ACS NSQIP wound occurrence variables may be indicated. Future iterations of the ACS NSQIP for Oncology and procedure-specific modules should expand the definition of wound occurrences to incorporate additional clinically relevant surgical outcome variables, including hematoma, seroma, percutaneous drainage procedures, lymph leak requiring prolonged drainage, skin necrosis, and delayed healing.

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TABLE 1

Characteristics of 281 patients who underwent ILND for cutaneous melanoma and 40 patients who developed a wound complication, and the association of each factor with wound complication in univariate analysis

phics mean (SD) 280) 247)				P value
(SD)	uency (%)	Frequency	(%)	
(SD)				
	5.4)	58.4 (11.5)		0.13
				0.61
	58.9%	22	13.3%	
	41.1%	18	15.7%	
				0.64
White 235	95.1%	33	14%	
Nonwhite 12	4.9%	7	16.7%	
Preoperative health				
BMI ($n = 277$)				< 0.01
Normal weight (BMI < 25) 74	26.7%	4	5.4%	
Overweight (BMI 25-30) 95	34.3%	10	10.5%	
Obese (BMI > 30) 108	39%	25	23.1%	
Diabetes ^a				0.05
No 251	87.4%	32	12.7%	
Yes 30	12.6%	8	26.7%	
Smoker^b				0.14
No 223	79.4%	28	12.6%	
Yes 58	20.6%	12	20.7%	
Alcohol drinker ^C				-
No 270	96.1%	39	14.4%	
Yes 11	3.9%	1	9.1%	
Dyspnead				0.68
No 269	95.7%	38	14.1%	
Yes 12	4.3%	2	16.7%	

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Characteristic	All patients $(n = 281)$	(n = 281)	Patients with a wour	Patients with a wound complication $(n = 40)$	<i>p</i> Value
	Frequency	(%)	Frequency	(%)	
Independent	277	98.6%	I	I	
Partially dependent	4	1.4%	I	I	
COPD					
No	278	98.9%	I	I	
Yes	3	1.1%	I	I	
CHF	0	%0	I	I	
CAD^f					0.14
No	265	94.3%	40	15.1%	
Yes	16	5.7%	0	0%	
PVD					
No	278	98.9%	I	I	
Yes	3	1.1%	I	I	
Renal failure ${\mathcal{S}}$	0	%0	I	I	
Hypertension h					0.11
No	187	66.5%	22	11.8%	
Yes	94	33.5%	18	19.1%	
History of stroke ^{<i>i</i>}					0.7
No	267	95%	39	14.6%	
Yes	14	5%	1	7.1%	
Steroid use					
No	277	98.6%	I	I	
Yes	4	1.4%	I	I	
Bleeding disorder					1
No	273	97.2%	39	14.3%	
Yes	8	2.8%	1	12.5%	
Chemo within 30 days k					1.00
No	274	97.5%	39	14.2%	
Yes	7	2.5%	1	14.3%	
Operation within 30 $days^{I}$					0.75

Characteristic	All patients $(n = 281)$	n = 281)	Patients with a wou	Patients with a wound complication $(n = 40)$	<i>p</i> Value
	Frequency	(%)	Frequency	(%)	
No	261	92.9%	38	14.6%	
Yes	20	7.1%	2	10.0%	
Laboratory values ^m					
WBC (n = 239)					
WBC <4.500	11	4.6%	I	I	
WBC 4.500–11,000	221	92.5%	I	I	
WBC >11,000	Т	2.9%	I	1	
Albumin ($n = 168$)					
< 3.4	7	4.2%	I	I	
> 3.4	161	95.8%	I	I	
Operative variables					
Extent of ILND ^{<i>II</i>}					0.02
Superficial	235	83.6%	28	11.9%	
Superficial + deep	46	16.4%	12	26.1%	
Wound class					1
Clean	269	95.7%	39	14.5%	
Clean-contaminated	12	4.3%	1	8.3%	
ASA class					0.45
1 No disturb	33	11.7%	3	9.1%	
2 Mild disturb	163	58%	22	13.5%	
> 3 Severe disturb	85	30.2%	15	17.6%	
Site of melanoma ⁰					0.73
Trunk	62	22.2%	8	12.9%	
Lower extremity	173	62%	27	15.6%	

BMI body mass index, COPD chronic obstructive pulmonary disease, CHF congestive heart failure; CAD coronary artery disease, PVD penipheral vascular disease, WBC white blood cell count, ASA American Society of Anesthesiology, INLD inguinal lymph node dissection

^aDiabetes mellitus requiring treatment

bUsed cigarettes in the year prior

 $\stackrel{\mathcal{C}}{>2}$ drinks/day in the 2 weeks before admission

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dDifficult, painful, or labored breathing

 ${}^{\!\!\!\!\!\!\!\!\!\!\!\!\!}^{}$ Ability to perform activities of daily living

f s presence of angina 1 month prior, myocardial infarction 6 months prior, previous percutaneous cardiac intervention, or previous cardiac surgery

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$^{\mathcal{S}}_{Acute or on dialysis}$ $h_{Requiring treatment}$

 \dot{H} istory of stroke with or without residual deficit or transient ischemic attack

JSteroid use for a chronic condition

kChemotherapy for malignancy within 30 days before surgery

I Major operation within 30 days

 ${}^{I\!I}\!\mathrm{D}_{\mathrm{rawn}}$ within 90 days before the surgical procedure

ⁿDefined by CPT codes

 o Site of primary melanoma, as specified by the ICD-9-CM code

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TABLE 2

Multivariate logistic regression analysis of wound complications in patients who underwent ILND for cutaneous melanoma

Predictor	Adjusted odds ratio	95% confidence interval	p value
Obese (vs. nonobese)	2.8	1.37–5.76	< 0.01
Diabetic (vs. nondiabetic)	2.52	1-6.4	0.05
Superficial + deep ILND (vs. superficial)	2.6	1.18-5.77	0.02

INLD inguinal lymph node dissection

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Article	Year	Data collection	u	Complication rate (%)		
Current Study	2012	Prospective	281	14	BMI >30	Age
					DM	Gender
					Extent of dissection	Smoker
Chang et al. ²	2010	Prospective	53	77	BMI >30	DM
						Extent of dissection
						Age
						Smoker
						Stage disease
Poos et al. ¹³	2009	Retrospective	139	50	BMI >25	Gender
					Age > 55 years	Smoker
					No hip immobilizer splint	Staff vs. fellow
						Operative time
						Indication
Sabel et al. ¹⁴	2007	Retrospective	212	19 (major)	BMI	Age
					Indication	Sex
						Number of LN removed
Serpell et al. ⁴	2003	Prospective	27	71	Size of largest LN	I
Hughes et al. ⁹	2000	Retrospective	132	49	1	Extent of dissection utilizing 2 incisions
Beitsch and Balch ¹¹	1992	Retrospective	168	51	Obesity	Depth of dissection
					Age > 50 years	Clinical stage
					Male	Prophylactic antibiotics
					Smoker	Nutritional status
					Clinically positive LNs	History of LE perfusion
						Number and duration of drains
						Synchronous surgery
Coit et al. ³	1991	Prospective	42	64	1	Perioperative antibiotic use