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Risk factors for post-operative complications after sentinel lymph node biopsy for cutaneous melanoma: Results from a large cohort study☆

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Summary *Background:* A sentinel lymph node (SLN) biopsy is a common surgical procedure for cutaneous melanoma. Our aim was to evaluate risk factors for early post-operative complications after SLN biopsy and to examine the impact of complications on health care resource utilisation.
Methods: We performed a retrospective cohort study including all adult patients who underwent a SLN biopsy for cutaneous melanoma in the Stockholm region from 2006 to 2014. Data of patient and tumour characteristics were collected from medical records, as well as information on complications and outpatient visits within 30 days from surgery. Risk factors were evaluated through logistic regression.
Results: Out of 886 patients who underwent SLN biopsy during the study period, 109 (12.3%) had one or several post-operative complications. The most common complication was a wound infection (7.7%), followed by seroma (6.4%). The risk of a post-operative complication was increased in patients with diabetes (odds ratio (OR) = 10.0, 95% confidence interval (CI) 4.0-24.6), who had inguinal location of SLN (OR = 2.7, 95% CI 1.7-4.3), who were male (OR = 1.9, 95% CI 1.2-2.9) and who had ulceration of the primary tumour (OR = 1.6, 95% CI 1.0-2.6). Individuals with post-operative complications had more visits to the outpatient clinic ($p < 0.05$).

☆ Preliminary results from this study were presented as the degree project of medical student E Laine in June 2018 (not published outside of Karolinska Institutet) and in the abstract form at the annual meeting of the Swedish Surgical Society in Helsingborg, Sweden, on August 24, 2018.

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Conclusion: Complications after SLN biopsy affect 12.3% of patients. Our results suggest that patients with diabetes, who had inguinal SLN biopsy and who were male have increased risk, and this might warrant more intense post-operative surveillance.

Introduction

The incidence of cutaneous melanoma is ever increasing and constitutes ~5% of new cancer cases annually in the Western world.[1,2] Plausible reasons for the increasing incidence include changing patterns of sun exposure.[3] Advanced melanoma carries a poor prognosis, with a five-year survival rate of only 20% for stage IV melanoma.[4,5]

Staging in melanoma requires nodal evaluation, which is performed through sentinel lymph node (SLN) biopsy. In Sweden, as in most other countries, an SLN biopsy is currently recommended for patients with intermediate-thickness melanomas (Breslow >1.0–4.0 mm) and thick melanomas (>4.0 mm) and may be considered for thin melanomas that are either 0.8–1.0 mm Breslow or <0.8 mm with ulceration.[6] An SLN biopsy not only provides important prognostic information but also directs further treatment.[7–10]

An SLN biopsy is generally considered a simple and safe surgical procedure; however, it is not free of complications. The risk of post-operative complications varies, but Moody et al. in his meta-analysis has shown the risk to be approximately 11%.[11] The most common complications are seroma and infection. Other less frequent but potentially more serious complications such as allergic reaction to the blue dye or radioactive colloid, deep vein thrombosis, pulmonary complications, cardiovascular complications and lymphoedema have also been reported following SLN biopsy but have not, with certainty, been attributable to the surgical procedure.[11,12] There have been few studies on the complication rates after SLN biopsy in patients of Swedish origin.

Postoperative complications are a significant reason for morbidity and mortality, and therefore, it is of great interest to patients and health care providers to identify modifiable risk factors for complications. Tumour characteristics such as histopathological melanoma type, melanoma stage and tumour thickness do not appear to impact the risk of complications.[13] However, attempts to evaluate and identify other potential risk factors have yielded inconclusive results. Primary sites of SLN biopsy are axillary and inguinal, and both locations have been associated with an increased risk of complications in different studies.[13,14] Furthermore, smoking, diabetes, high BMI and male gender have all been identified as possible risk factors for complications or readmission in some studies, but not all.[13,15,16] Like Moody et al. conclude in their meta-analysis, further studies with high-quality data are needed to determine how patient and tumour characteristics impact the risk of complications.[11]

It is well known that post-operative complications also affect health care resource utilisation and hospital costs.[17,18] Patients who develop a surgical site infection constitute a financial burden approximately double that of patients who do not develop such a complication.[19] Rosemurgy et al. have shown that reduction in surgical site infections can lead to potential cost savings for the health care system.[20] Patients with advanced melanoma have a diverse use of health care system services and high health care resource utilisation, but to the best of our knowledge, the impact of complications after SLN biopsy on health care resource utilisation has not yet been investigated.[21,22]

Consequently, the purpose of this study was to assess the risk of complications after SLN biopsy for melanoma in adults and to examine the impact of patient and tumour characteristics on that risk. Our secondary aim was to evaluate the impact of complications on health care resource utilisation.

Materials and methods

The study was approved by the Ethical Review Board of Stockholm, 2017/795-31 and 2018/1853-32. The manuscript was prepared according to the STROBE (Strengthening the reporting of observational studies in epidemiology) Statement® (https://www.strobe-statement.org) guidelines.

We performed a retrospective cohort study including all adult patients who underwent SLN biopsy for cutaneous melanoma in the Stockholm region from 1 January 2006 to 31 December 2014.

During the study period, an SLN biopsy was considered for patients who had a primary melanoma thicker than 1.0 mm Breslow or thinner than 1.1 mm Breslow but with ulceration. An SLN biopsy was not usually performed in our unit for melanoma of the head and neck region. It was also not considered in patients with locoregional or distant metastasis. The technique used for SLN biopsy at our units is the standard method of preoperative Technetium^{99}-based lymphoscintigraphy, followed by determining the intraoperative location of the node(s) using a hand-held gamma probe using a blue dye.[23] The SLN biopsy was usually performed as a day-case procedure with occasional patients requiring overnight stay depending on the patient's recovery after anaesthesia.

All SLN biopsies for melanoma in the Stockholm region are performed at Karolinska University Hospital or at Södersjukhuset (Stockholm South General Hospital). Patients who had been treated at Karolinska University Hospital were identified through electronic medical records and a prospectively collected patient register maintained by the contact nurse for this patient group. Patients who had been treated at Södersjukhuset were identified through a separate register kept by the surgeon in charge (PG). Exclusion criteria were age under 18 years, missing pathologist's

report and inaccessible medical records. Patient characteristics including age, sex, BMI, smoking status and a diagnosis of diabetes were collected from the medical records, as were details on the primary tumour such as localisation, histological subtype, Breslow thickness and Clark level. Furthermore, clinical outcomes including SLN biopsy result, numbers of readmissions to the inpatient ward or return visits to the outpatient clinic and diagnosis of post-operative complications within 30 days of surgery were also assembled through manual review of medical records. Antibiotics were only used if there were clinical signs and symptoms of infection, such as redness, swelling or tenderness, at the site of SLN biopsy. Seromas and haematomas were considered clinically significant and recorded if they required surgical interventions such as needle aspiration or return to theatre.

Records were maintained for any unscheduled outpatient or inpatient attendances in the first 30 days following surgery.

Statistical analysis

Patient demographics and tumour characteristics were compared against the relative risk of post-operative complications using non-paired *t*-test for continuous variables (BMI and age), chi-square test for two binary variables (sex, diabetes and ulceration of primary tumour) and ANOVA for different categories of variables (smoking and site of SLN biopsy). Smoking was tested as a binary variable (divided as smokers versus non-smokers) and BMI as categorical data ($<$18.50, 18–50–24.99 and $>$24.99 kg/m^2). Further assessment of the risk of post-operative complications was performed through multivariable logistic regression models. Multivariable logistic regression was performed using the forward elimination procedure ($p < 0.10$ for model entry). All visits, planned and unplanned, to the surgical outpatient clinic 30 days post-operatively were counted. Testing of difference in mean values between groups was performed through a two-paired *t*-test. Results are reported using 95% confidence intervals and *p*-values. Statistical analyses were performed using Stata/IC 13 (StataCorp LP, Texas, USA).

Results

The characteristics of the 886 included patients are given in Table 1. Mean age at surgery was 57.4 years, and a majority of the procedures were performed at Karolinska University Hospital. The health status of the study population is given in Table 2. A known diagnosis of diabetes was uncommon (2.5%), mean BMI was 26.3 kg/m^2 and 16.0% of the individuals in the cohort were known to be current or previous smokers.

Among the 886 individuals who underwent SLN biopsy, 109 (12.3%) patients had one or more post-operative complications within 30 days of surgery. The most common complication was a wound infection (7.7%), followed by seroma (6.4%) (Table 3). One patient developed a rash that was believed to be due to the blue dye, one patient reported sensory loss distal to the area of the surgical site and one patient had an acute myocardial incident three days post-operatively. In total, 18 patients required readmission to the hospital: one patient with an acute myocardial incident and 17 patients with infection. No patient had a complication that required return to theatre.

Table 1 Characteristics of the study population. Patients undergoing sentinel lymph node biopsy in Stockholm, 2006–2014.

All patients	886
Sex	
Male	459 (51.8%)
Female	427 (48.2%)
Age in years, mean (range)	57.4 (18–91)
18–39	82 (9.3%)
40–59	352 (39.7%)
60–79	444 (50.1%)
80–91	8 (0.9%)
Site	
Karolinska University Hospital	817 (92.2%)
Södersjukhuset	69 (7.8%)
Site of melanoma	
Lower limb	307 (34.7%)
Upper limb	158 (17.8%)
Trunk anterior	127 (14.3%)
Trunk posterior	291 (32.8%)
Head and neck	3 (0.3%)
Ulceration	
No	626 (70.7%)
Yes	234 (26.4%)
Unclear/unknown	26 (2.9%)
Clark level	
II	3 (0.3%)
III	162 (18.3%)
IV	682 (77.0%)
V	8 (0.9%)
Unclear/unknown	31 (3.5%)
Thickness in mm, mean (range)	2.5 (0.5–22)
Thin ($<$1.2 mm)	51 (5.8%)
Intermediate (1.2–3.5 mm)	673 (76.0%)
Thick ($>$3.5 mm)	161 (18.2%)
Unclear/unknown	1 (0.1%)
Histopathological type	
Superficial spreading melanoma	432 (48.8%)
Lentigo maligna melanoma	13 (1.5%)
Acral lentiginous melanoma	21 (2.4%)
Nodular melanoma	175 (19.8%)
Other/unclear/unknown	245 (27.7%)
Site of SLN biopsy	
Inguinal	321 (36.2%)
Axillary	548 (61.9%)
Other	17 (1.9%)

Risk factors for postoperative complications

We assessed the association between having one or several post-operative complications and age, sex, smoking status, diabetes, BMI and site of SLN biopsy. The mean age for

Table 2 Health status of the study population. Patients undergoing sentinel lymph node biopsy in Stockholm, 2006-2014.

All patients	886
Diabetes	
Yes	22 (2.5%)
No	794 (89.6%)
Unknown	70 (7.9%)
BMI, mean (range)	26.3 (16.6-55.4)
<18.5	5 (0.6%)
18.5-24.99	327 (36.9%)
≥25	482 (54.4%)
Unknown	72 (8.1%)
Current smoking status	
Never smoker	530 (59.8%)
Current smoker	93 (10.5%)
Previous smoker	48 (5.4%)
Pre-surgery cessation	1 (0.1%)
Unknown	214 (24.2%)
Known (ever) smoker	
Yes, smoker	142 (16.0%)
No, non-smoker	744 (84.0%)

Table 3 Complications after sentinel node biopsy in the study population. The total number of patients, $n = 886$.

Complication	Number of patients (%)
Infection	68 (7.7)
Seroma	57 (6.4)
Wound rupture	5 (0.6)
Haematoma	4 (0.5)
Lymphoedema	4 (0.5)
Other	3 (0.3)
Total	**109 (12.3)**[a]

[a] The added number of complications exceeds the total number of patients because some patients had more than one complication.

patients with complications was 55.4 years, whereas it was 57.6 years for those without complications ($p = 0.083$). The complication rate was higher in men (14.2%) than in women (10.3%), but the difference was not statistically significant ($p = 0.081$). The proportion of complications was insignificantly higher in patients who had never smoked (12.8%) than in ever smokers (9.9%) ($p = 0.333$). The complication rate was higher in patients with diabetes (54.6%) versus those without (11.5%) ($p < 0.001$). There was no mean difference in the BMI (26.5 versus 26.3 kg/m^2) between patients with complications and those without. SLN biopsies performed in the inguinal region had a higher rate of complications (19.0%) than SLN biopsies performed in the axillary region (8.8%) ($p < 0.001$). Melanomas located on the lower extremity had a higher complication rate at the site of SLN biopsy than melanomas in other locations (Table 4) ($p = 0.007$). Melanomas with primary ulceration were more often associated with post-operative complications resulting from the SLN biopsy (16.2%) than

Table 4 Complications after sentinel node biopsy in the study population by melanoma location. Total number of patients, $n = 886$.

Location	Patients with complications (%)
Lower limb	55 (17.9%)
Trunk posterior	29 (10.0%)
Upper limb	14 (8.9%)
Trunk anterior	11 (8.7%)
Head and neck	0 (0%)
Total	**109 (12.3)**

Table 5 Complications after sentinel node biopsy in the study population by melanoma subtype. Total number of patients, $n = 886$.

Subtype	Patients with complications (%)
Superficial spreading melanoma	44 (10.2%)
Nodular melanoma	22 (12.6%)
Acral lentiginous melanoma	7 (33.3%)
Lentigo maligna melanoma	2 (15.4%)
Other/unclear/unknown	34 (13.9%)
Total	**109 (12.3)**

melanomas without primary ulceration (11.0%) ($p = 0.039$). Acral lentiginous melanomas (ALM) were associated with an increased risk of complications (33.3%) as compared to other histopathological subtypes ($p = 0.026$) (Table 5). Breslow thickness of the melanoma was not associated with the risk of complications ($p > 0.005$).

Age, sex, smoking, diabetes, BMI, location of SLN, ulceration and histopathological subtype were further assessed by logistic regression. Adjusted and crude odds ratios (ORs) are given in Table 6. The risk of a post-operative complication was increased in individuals with diabetes (OR = 10.0, 95% confidence interval (CI) 4.0-24.6), who were male (OR = 1.9, 95% CI 1.2-2.9), who had inguinal location of SLN (OR = 2.7, 95% CI 1.7-4.3) and who had ulceration in the primary tumour (OR = 1.6, 95% CI 1.1-2.6) in the final, multivariate model adjusted for age.

Health care resource utilisation

During the 30-day post-operative follow-up, individuals with complications had more visits to the outpatient clinic than individuals without complications ($p < 0.05$). The median number of doctor appointments for individuals with complications was two (range 0-5) as compared to that of one for those without complications (range 0-3). The median number of nurse appointments for individuals with complications was two (range 0-6) as compared to that of one for those without complications (range 0-3).

In the group of individuals without complications, the total number of post-operative clinic appointments was 758, with a mean of 1 appointment per person (0.976). In the group of individuals with complications, the total number of post-operative clinic appointments was 206, with a mean

Table 6 Association between risk of complications and potential risk factors. Total number of patients, $n = 886$.

Assessed variable	Unadjusted			Adjusted		
	OR	*p*-value	95% CI	OR	*p*-value	95% CI
Age	1.0	0.083	1.0-1.0	1.0	0.027	1.0-1.0
Sex (male)	1.4	0.082	1.0-2.2	1.8	0.020	1.1-2.8
Smoking	0.7	0.335	0.4-1.4	0.7	0.337	0.4-1.4
Diabetes	9.3	<0.001	3.9-22.1	12.2	<0.001	4.5-33.1
Body mass index	1.0	0.523	1.0-1.1	1.0	0.640	1.0-1.1
Site of SLN (inguinal)	2.1	<0.001	1.4-3.2	2.5	<0.001	1.5-4.0
Ulceration	1.6	0.040	1.0-2.4	1.8	0.023	1.1-2.9
Subtype (ALM)	3.1	0.023	1.2-8.2	1.5	0.507	0.45-5.0

OR = odds ratio, CI = confidence interval, SLN = sentinel lymph node.

of 2 appointments per person (1.890). The cost per patient for SLN biopsy performed as a day case in our unit is calculated at 29,870 SEK (Swedish krona) (numbers from 2019). The cost per patient for a clinic appointment under the diagnosis of melanoma and post-operative complication is 3700 SEK, and admittance is calculated at 74,542 SEK per patient.

Discussion

In this retrospective cohort study of nearly 900 patients, we found a 12.3% complication rate after SLN biopsy for cutaneous melanoma. The site of SLN biopsy, male gender, diabetes and ulceration were found to be associated with an increased risk of post-operative complications, which were in turn linked to increased health care resource utilisation.

Our post-operative complication rate of 12.3% is slightly lower than the rate reported in a large cohort presented by Morton et al. and in line with that of a recently published systematic review, which, based on 21 studies, found an overall risk of 11.3%.[11,12] The rates of different types of complications in our study are similar as those reported in previous studies, where infection and seroma have also been the most common complications.[11,12] In our cohort, these two conditions overlapped to a large extent. The lower rate of lymphoedema in our study could be due to the follow-up cut-off at 30 days post-operatively.

Severe complications are rare after SLN biopsy, as confirmed in our study. One included patient suffered an acute myocardial incident three days post-operatively, which may or may not have been linked to the surgery and anaesthesia of the SLN procedure.

In our study, the largest risk factor identified was diabetes, which increased the risk of complications tenfold. This has been shown in one previous study, although not to such a great extent, and only in association with inguinal SLN biopsy.[15] Lower limb melanoma or inguinal SLN were risk factors for complications, which confirms the results from previous studies.[13,14] Similarly, male sex has previously been identified as a risk factor for hospital readmission after SLN biopsy.[15] In contrast to one previous study, we could not detect a correlation between smoking and post-operative complications.[15] In our analyses, smoking was tested as both a categorical variable and a binary variable. Other previous studies have also failed to link smoking to an increased risk of post-operative complications.[13,16] One prior investigation has shown a correlation between post-operative complications and BMI, which we could not replicate in our study.[13] In our data, there was a trend towards increased number of complications with increasing BMI, but this was not statistically significant.

To the best of our knowledge, this is the first study to demonstrate an increased risk of post-operative complications in individuals with an ulcerated primary tumour. This is a curious finding, especially considering that a majority of patients undergoing SLN biopsy at our units have had their primary tumours excised with radical margins before their SLN procedure. In the group of ulcerated melanomas, a larger number of excisions had involved margins (12%) than the rest of the cohort (7.2%) ($p = 0.002$). This might have contributed to a higher rate of open, contaminated wounds at the time of SLN biopsy, leading to more infections. Indeed, infections were by far the most common complication among individuals with ulcerated melanomas (11.1%). Furthermore, ulcerated melanomas are known to carry a worse long-term prognosis, and information of ulceration can be used to predict lymph node status.[24] Unfortunately, we did not have clinical information on which patients were given prophylactic antibiotics pre- or post-operatively.

We found that individuals with ALM had an increased risk of post-operative complications; however, when adjusted for multiple variables including site of SLN biopsy, the risk was no longer statistically significant. This could be due to lack of power in our study to detect a true correlation between the histopathological subtype and complication risk; however, it is more likely to be due to confounding by location, as almost all melanomas of ALM type are located on the lower limb.

We found that individuals with complications had more post-operative visits to the outpatient clinic than individuals without complications. This finding is in line with those reported in previous studies on health care resource utilisation and costs associated with post-operative complications.[17-19] Because complications appear to require at least one additional clinic appointment at 3700 SEK, this is the estimated average cost per patient with complications (excluding rare cases needing re-admission). For a unit performing 130 SLN biopsies annually, a complication rate of 12.3% will add a cost of 59,200 SEK yearly through addi-

tional clinic appointments. The finding of increased health care resource utilisation is unsurprising, but nevertheless, it offers a foundation for incentives to decrease complication rates further. Additionally, there is a risk that complications delay further treatment, but we have not investigated this risk in the current study.

The strengths of our study include its large size, population-based setting and reliable data. One of its limitations is the potential cause of confounding inherent in retrospective data collection methods. Furthermore, minor variations in the surgical technique for the SLN biopsy may have occurred during the study period, as well as slight differences in treatment protocols. Nevertheless, with regard to the large study size, any non-differential biases should affect only the estimates towards the null. We did not have access to medical records from other institutions apart from our own; thus, there is a risk that the number of complications is underestimated in our cohort if patients have sought help elsewhere. However, this should be a negligible number because all patients have had easy and direct access to the outpatient clinic at our units. Furthermore, we distinctly encourage our patients at discharge to contact us in case of any questions or complications, and in our experience, our patients tend to want to turn to their surgery clinic when complications arise instead of their primary care physician.

In conclusion, in this retrospective cohort study of approximately 900 Swedish patients with cutaneous melanoma, we observed a 12.3% complication rate, and we confirmed diabetes, inguinal location of SLN and male gender and identified ulceration of the primary tumour as risk factors for post-operative complications. Previous findings on smoking and BMI as risk factors could not be replicated in this study. Our results underline the importance of accurate preoperative information to patients undergoing even minor surgery.

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Declaration of Competing Interest

The authors have no conflicts of interest to disclose.

Supplementary materials

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