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Completion lymph node dissection for merkel cell carcinoma

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ABSTRACT

Background: Sentinel lymph node biopsy (SLNB) is widely used for Merkel cell carcinoma (MCC), however in SLNB positive MCC the role of completion lymph node dissection (CLND) with or without adjuvant radiation therapy is unclear.
Objective: Our goal was to determine the impact of CLND and adjuvant radiation therapy on survival in SLNB positive MCC.
Materials and methods: We examined 447 patients with MCC with a positive SLNB in the National Cancer Data Base from 2012 to 2015. We compared patients who underwent CLND versus observation with or without adjuvant radiation.
Results: Compared with CLND and adjuvant radiation (reference) treatment with observation (HR 3.54, CI 1.36–9.18) or CLND alone (HR 2.54, CI 1.03–6.27) were associated with worse overall survival after adjusting for clinicopathologic differences. In contrast treatment with adjuvant radiation alone without CLND was not associated with worse overall survival (HR 1.70, CI 0.74–3.92) compared with CLND and adjuvant radiation (reference).
Conclusions: In SLNB positive MCC, CLND alone is associated with worse survival compared with treatment with adjuvant radiation or both CLND and adjuvant radiation.

Introduction

Merkel cell carcinoma (MCC) is a rare and aggressive cutaneous malignancy associated with infection with Merkel cell polyomavirus or DNA damage from ultraviolet radiation.[1] Nearly half of MCC occurs on skin of the head and neck.[2] The incidence of MCC is rising,[3] however level I data are lacking to support many practices. Therefore, many clinicians apply lessons learned from melanoma, where level I evidence does exist to guide management.[4] While there are some similarities between MCC and melanoma, the prognosis of MCC is significantly worse.[5] Thus, it is important to validate these management paradigms for MCC.

Sentinel-lymph node biopsy (SLNB) is associated with improved melanoma-specific survival in patients with intermediate thickness melanoma and nodal metastases[4] and has become widely adopted for the staging of nodal disease in melanoma.[6] Several single-institution reports have described outcomes after SLNB for MCC,[7–9] and based on this limited data SLNB has been recommended in guidelines for all non-metastatic, clinically node negative MCC.[10] While patients with a positive sentinel node biopsy traditionally underwent completion lymph node dissection (CLND), recent evidence from the Multicenter Selective Lymphadenectomy Trial-II (MSLT-II) trial for melanoma questions the need to perform a CLND when nodal metastases are identified by SLNB,[11] calling into question the utility of CLND in MCC. Further complicating decision-making MCC is radiosensitive and adjuvant radiation therapy (RT) plays a more prominent role in MCC than in melanoma.

Currently, National Comprehensive Cancer Network Guidelines recommend that patients with sentinel lymph node (SLN) positive MCC undergo “nodal dissection and/or RT to the nodal basin.”[10] However, these guidelines provide little information to help make the decision about the benefits of these potential options in SLN positive patients. We set out to provide greater evidence to help guide decision-making about the benefits of CLND, adjuvant RT or both in SLNB positive MCC.

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Materials and methods

Data acquisition and patient selection

We used the National Cancer Data Base (NCDB) to identify patients older than 18 years of age with cT1-T4, cN0, cM0 MCC that underwent SLNB with SLN positive from January 1st, 2012 to December 31st, 2015. These dates were selected because the NCDB did not include a variable for SLNB prior to 2012, and the most recent year available at the time of analysis was 2015. The NCDB is a national oncology outcomes registry of the American College of Surgeons, the Commission on Cancer and the American Cancer Society. The NCDB collects data from over 1450 Commission on Cancer hospitals in the United States including approximately 70% of all new cancers diagnosed each year.[12] We used the International Classification of Diseases for Oncology, Third Edition codes to identify patients with MCC (histology codes 8247). Patients were initially staged in the NCDB using American Joint Committee on Cancer Seventh Edition guidelines, however to improve clinical applicability we re-staged using the changes in the Eighth Edition. pN1a (sn) disease was defined as nodal involvement that was clinically N0 but positive on SLNB. We excluded patients with distant metastases (n = 453), clinical evidence of LN metastases (n = 1372), who did not undergo primary site surgery (n = 274), who underwent LN aspiration as a means of regional staging (n = 29) or who were missing staging information (n = 373), did not undergo SLNB (n = 1933), had a negative SLN (n = 1378).

Patients were grouped based on the type of therapy received after a positive SLNB including either observation, CLND, adjuvant RT or CLND and adjuvant RT. Patients treated with CLND and adjuvant RT were treated as the reference group as they accounted for 48.3% of patients.

Statistical analysis

Categorical variables were compared using a Chi-square test except when expected values were <5 in which case a Fisher's exact test was substituted. Length of stay after surgery was determined to be nonparametric and a Mann-Whitney *U* test was used to compare this outcome.

The primary outcome measure was overall survival (OS). Differences in OS were compared using a log rank test. Times of survival were calculated by the Kaplan-Meier method. Cox-proportional hazard models were developed to test the association between type of additional treatment (observation, CLND, adjuvant RT or CLND and adjuvant RT) and death after adjustment for sex, age, race, Charlson comorbidity score, anatomical subsite, T classification, number of positive LN, surgical margins, hospital volume and year of diagnosis. Variables were selected for inclusion based upon both biological and clinical relevance and statistical significance.[13] Proportional hazard assumptions were confirmed graphically. Sensitivity analysis was performed in several subgroups to confirm the robustness of the results. All p-values were two-sided and a statistical level of significance was set to 0.05. Statistical analyses were performed with SPSS, version 24 (IBM, Armonk, NY). The Wayne State University Institutional Review Board approved a waiver for this study.

Results

Characteristics of study cohort and SLNB

We identified a cohort of 447 patients with SLN positive MCC that met our inclusion and exclusion criteria. After positive SLNB observation was performed for 71 patients (15.9%), CLND was performed for 64 patients (15.2%), adjuvant RT alone was performed for 216 patients (48.3%), and CLND and adjuvant RT were performed for 96 patients (21.5%). Table 1 shows the patient characteristics for our cohort. Patients that were treated with both CLND and adjuvant RT were younger. Patients treated with CLND alone or in combination with adjuvant RT had less comorbidities.

The characteristics of the lymph nodes removed during surgery are shown in Table 2. In the SLNB alone group a median of 2.0 lymph nodes (standard deviation (SD) 1.6) were removed compared with a median of 16.0 lymph nodes (SD 18.9) in the CLND group.

Adverse events associated with regional LN evaluation

The mean length of stay after surgery was 0.9 days (SD 6.0) for SLNB alone and 1.9 days (SD 8.0) for CLND. Mortality at 90-days was 1.1% with SLNB alone, and 0.0% with CLND. Readmission within 30-days of surgery occurred in 1.9% with SLNB alone and 0% with ELND.

Unadjusted Overall Survival

Median follow up for survival analyses was 33.4 months (range 0.01–59.5 months). Three year OS was 63.9% without CLND versus 69.3% with CLND (Log rank p = 0.169). In comparison, 3-year OS was 49.2% without adjuvant RT versus 70.5% with adjuvant RT (Log rank p = 0.001). When considering both CLND and/or adjuvant RT 3-year OS was 50.0% without CLND and without adjuvant RT, 52.9% with CLND and without adjuvant RT, 67.9% with adjuvant RT alone and 79.5% with CLND and with adjuvant RT (Log rank p = 0.008, Fig. 1).

Adjusted Overall Survival

We performed multivariable Cox-proportional hazard models to adjusted for clinicopathologic differences shown in Fig. 2 and Table 3. We first examined the impact of either CLND or adjuvant RT when considered separately. On adjusted analyses CLND was not associated with an improvement in OS (HR 0.62, CI 0.33–1.16). In contrast, on adjusted analysis adjuvant RT was associated with improved OS (HR 0.48, CI 0.28–0.82). We next considered the combined impact of CLND and/or adjuvant RT. On adjusted analysis observation (HR 3.54, CI 1.36–9.18) and CLND alone (HR 2.54, CI 1.03–6.27) were associated with worse OS compared with CLND and adjuvant RT (reference). On adjusted analysis adjuvant RT alone (HR 1.70, CI 0.74–3.92) was not significantly associated with worse OS compared with CLND and adjuvant RT.

The primary anatomic site of MCC significantly impacted survival. In adjusted analysis patients with upper limp and shoulder MCC (HR 0.42, CI 0.19–0.91) had significantly better OS compared with trunk/other skin MCC (HR 0.46, CI 0.18–115), lower limb and hip MCC (HR 0.81, CI 0.38–1.74) or patients with head and neck MCC (reference).

Subgroup analysis by age

We performed additional subgroup analysis based on age as the risk and benefits of CLND or adjuvant RT were affected. In the subset of patients ≥75 years old, the benefits of additional treatment after a positive SLNB were diminished (HR 2.38, CI 0.66–8.59 for observation; HR 1.84, CI 0.53–6.36 for CLND alone; HR 0.93, CI 0.28–3.16 for adjuvant RT alone; reference for CLND and adjuvant RT).

Discussion

We investigated the role of CLND with or without adjuvant RT after identification of a metastatic sentinel node. We find that

Table 1
Study cohort demographics and clinical characteristics.

Variable	Overall Cohort (n = 447) N (%)	Observation (n = 71) N (%)	CLND alone (n = 64) N (%)	Adjuvant RT alone (n = 216) N (%)	CLND and Adjuvant RT (n = 96) N (%)
Sex					
Male	292 (65.3)	47 (66.2)	46 (71.9)	132 (61.1)	67 (69.8)
Female	155 (34.7)	24 (33.8)	18 (28.1)	84 (38.9)	29 (30.2)
Age					
<65 years	77 (17.2)	31 (14.4)	7 (9.9)	16 (25.0)	23 (24.0)
65–75 years	146 (32.7)	82 (38.0)	14 (19.7)	19 (29.7)	31 (32.3)
75–84 years	161 (36.)	76 (35.2)	30 (42.3)	20 (31.3)	36 (36.5)
≥85 years	63 (14.1)	27 (12.5)	20 (28.3)	9 (14.1)	7 (7.3)
Race					
White	426 (95.3)	64 (90.1)	61 (95.3)	207 (95.8)	94 (97.9)
African American	4 (0.9)	2 (2.8)	0 (0)	1 (0.5)	1 (1.0)
Other	7 (1.6)	5 (7.0)	2 (3.1)	0 (0)	0 (0)
Hispanic	10 (2.2)	0 (0)	1 (1.6)	8 (3.7)	1 (1.0)
Charlson/Deyo comorbidity index					
0	320 (71.6)	49 (69.0)	49 (76.6)	147 (68.1)	75 (78.1)
1	95 (21.3)	14 (19.7)	13 (20.3)	52 (24.1)	16 (16.7)
≥1	32 (7.2)	8 (11.3)	2 (3.1)	17 (7.9)	5 (5.2)
Clinical T-classification					
T1	207 (46.3)	37 (52.1)	30 (46.9)	96 (44.4)	44 (45.8)
T2	222 (49.7)	28 (39.4)	30 (46.9)	114 (52.8)	50 (52.1)
T3	15 (3.4)	4 (5.6)	4 (6.3)	6 (2.8)	1 (1.0)
T4	3 (0.7)	2 (2.8)	0 (0)	0 (0)	1 (1.0)
Subsite					
Head and neck	151 (33.8)	24 (35.3)	25 (43.1)	58 (29.0)	28 (31.5)
Upper limb and shoulder	133 (29.8)	19 (27.9)	18 (31.0)	55 (27.5)	35 (39.3)
Lower limb and hip	102 (22.8)	12 (17.6)	7 (12.1)	61 (30.5)	14 (15.7)
Trunk/other skin	61 (13.6)	13 (19.1)	8 (13.8)	26 (13.0)	12 (13.5)
Surgical margins					
Negative	398 (90.5)	64 (92.8)	60 (95.2)	186 (87.3)	88 (92.6)
Positive	42 (9.5)	5 (7.2)	3 (4.8)	27 (12.7)	7 (7.4)
Hospital volume					
Lowest tercile	113 (25.3)	16 (23.5)	8 (13.8)	62 (31.0)	20 (22.5)
Middle tercile	143 (32.0)	28 (41.2)	17 (29.3)	61 (30.5)	28 (31.5)
Highest tercile	191 (42.7)	24 (35.3)	33 (56.9)	77 (38.5)	41 (46.1)

Abbreviations: SLNB = sentinel lymph node biopsy, CLND = completion lymph node dissection, RT = radiation therapy.

Table 2
Characteristics of lymph nodes removed during surgery.

Variable	SLNB Only (n = 287) N (%)	SLNB & CLND (n = 160) N (%)
Number of lymph nodes examined		
1-3	240 (83.6)	17 (10.6)
4-10	47 (16.4)	31 (19.4)
11-17	0 (0)	39 (24.4)
18+	0 (0)	73 (45.6)
N-classification		
pN1a (sn)	268 (93.4)	148 (91.5)
pN2	10 (3.5)	0 (0)
pN3	9 (3.1)	12 (7.5)
Number of lymph nodes positive		
1	214 (74.6)	70 (43.8)
2-3	66 (23.0)	67 (41.9)
4+	7 (2.4)	23 (14.4)
Size of lymph node metastasis (n = 237)		
<0.1 mm	134 (46.7)	76 (47.5)
0.1–1.0 mm	37 (12.9)	32 (20.0)
>1.0 mm	52 (18.1)	14 (8.8)
Extracapsular Extension (n = 403)		
Present	39 (13.6)	13 (8.1)
Absent	248 (86.4)	147 (91.9)

Abbreviations: SLNB = sentinel lymph node biopsy, CLND = completion lymph node dissection.

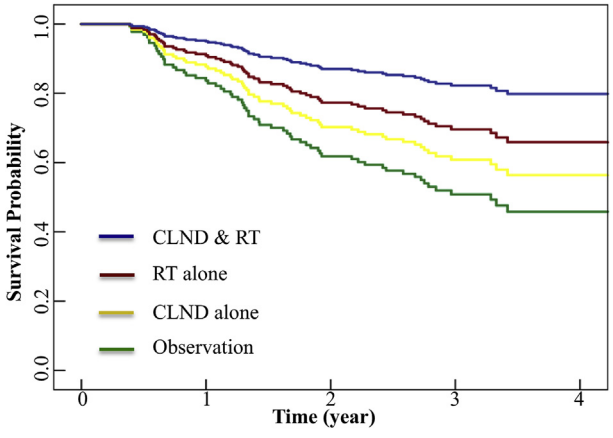

Fig. 1. Kaplan Meier Overall Survival for Sentinel Lymph Node Positive Merkel Cell Carcinoma Based on Type of Adjuvant Treatment
Abbreviations: CLND = completion lymph node dissection, RT = radiation therapy.

adjuvant radiotherapy alone or adjuvant RT combined with a CLND following a positive sentinel node was associated with improved OS. In contrast CLND alone or observation were associated with worse survival.

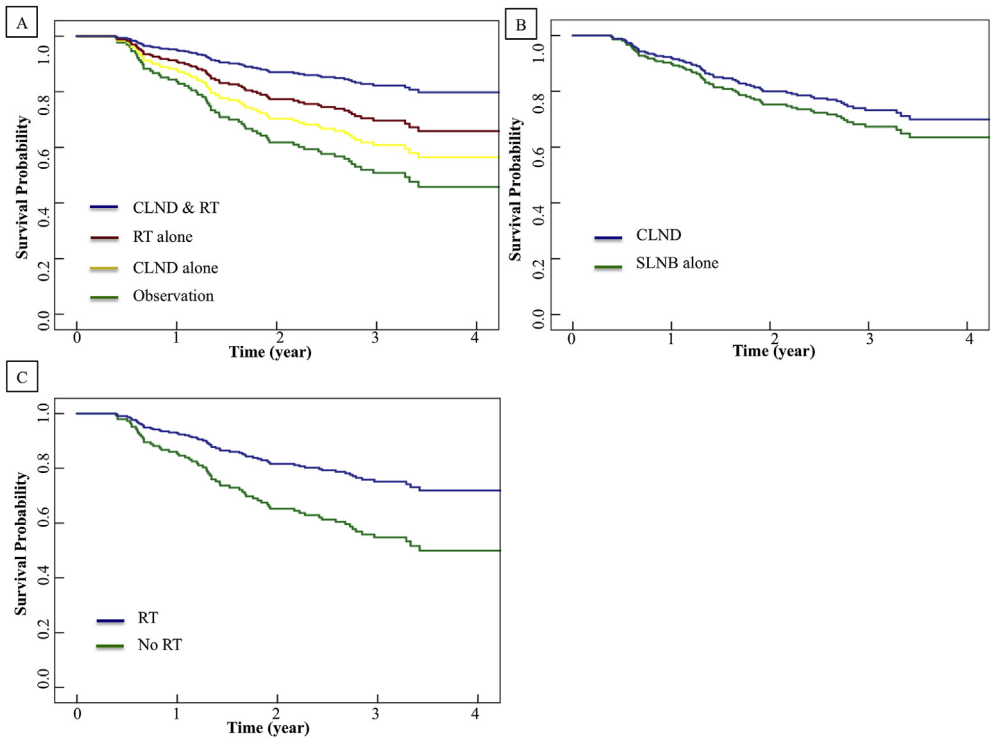

Fig. 2. Cox-Proportional Hazard Model of Overall Survival in Sentinel Lymph Node Positive Merkel Cell Carcinoma based on type of Additional Treatment
A: Adjusted for CLND and/or adjuvant RT when considered as a single variable. B: Primarily adjusting for CLND when considered as a single variable. C: Assessing adjusting for adjuvant RT.

After identification of a metastatic sentinel LN, current National Comprehensive Cancer Network guidelines for MCC recommend a CLND and/or radiation therapy to the nodal basin.[10] However recent data from the Multicenter Selective Lymphadenectomy Trial-II (MSLT-II) trial in melanoma question the value of CLND.[11] MSLT-II found that immediate CLND in patients with a positive SLNB improved regional disease control but did not prolong melanoma-specific survival. Furthermore, CLND was associated with significant morbidity with 24.1% of patients developing lymphedema.[11]

In contrast MCC has several distinctive characteristics complicating decision-making regarding the role of CLND after a positive SLNB. First, MCC carries the worst prognosis of any form of skin cancer.[5] Second, MCC patients are typically elderly increasing the perioperative risks of CLND,[14] Finally, unlike melanoma MCC is highly responsive to adjuvant RT,[15] and adjuvant RT may obviate the need for CLND.

Few other studies have looked at CLND or adjuvant RT in MCC. Perez et al. conducted a retrospective single-institution study examining 71 MCC patients with SLNB positive disease.[16] After 22 months of follow up regional recurrence rates were 7.5% for patients that underwent SLNB only and adjuvant RT, 9.0% for patients that underwent CLND without adjuvant RT and 0% for patients that underwent CLND and adjuvant RT. OS was not significantly different.[16] They concluded that "CLND alone or radiation monotherapy appears to be sufficient in the management for the majority of patients with micrometastatic regional lymph node MCC." Another study by Lee et al. arrived at a similar conclusion. They conducted a prospective study enrolling 163 patients comparing CLND vs. adjuvant RT in SLNB-positive patients. They found no significant differences in survival between the two groups.[17] A third study by Fang et al. conducted a study evaluating radiation monotherapy vs. CLND for regional management of lymph node positive MCC; only 26 patients in their cohort presented with microscopic nodal disease, and in this subset there was no survival difference between CLND and RT.[15] Lastly, Bhatia et al. found that adjuvant RT improved OS only for patients with stage I-II MCC but not for stage III MCC (including all patients with regional lymph node metastases).[18] However, this study did not examine the extent of regional lymph node surgery in relation to adjuvant RT.

In our analysis, we found that adjuvant RT significantly improved OS while CLND did not. Despite a 5.4% absolute increase in unadjusted OS with CLND, after adjusting for potential confounders CLND was not associated with improved OS. In comparison, adjuvant RT was associated with a 21.3% increase in unadjusted OS in this same population, emphasizing the importance of considering both CLND and adjuvant RT. When considering both of this important treatment factors we found that adjuvant RT alone and CLND with adjuvant RT were associated with improved survival compared with CLND alone or adjuvant RT. On adjusted analysis, adjuvant RT was independently associated with improved OS, suggesting that adjuvant RT should be considered for SLN positive patients, and is not equivalent to CLND (in contrast to the findings of the studies discussed above). Although, OS with adjuvant RT alone versus both CLND and adjuvant RT did not significantly differ, the hazard ratio of 1.70 indicated a potential benefit for both CLND and adjuvant RT that may be detected in a larger study. Of note, our data only included 447 patients with a SLN positive MCC.

We would advocate for either adjuvant RT alone or CLND and adjuvant RT for SLN positive MCC patients. Determining the optimal of these two strategies requires individualized approach. In younger patients with less comorbidities, CLND may offer benefit. Supporting this, we observed that patients <75 years old observed a significant benefit from CLND. Similarly, in patients with MCC requiring CLNB of regions where the risks of lymphedema are decreased the benefits of CLND may outweigh the risks. For example, in MSLT-I the risk of lymphedema was 9% with axillary versus 26% with inguinal basin dissection.[19] However, in elderly patients, those with severe comorbidities, or at high risk for postoperative lymphedema CLND may not

Table 3
Cox-proportional hazard regression analysis of survival based on type of treatment after a positive sentinel lymph node biopsy.

Variable	HR	CI
Lymph node assessment		
CLND and adjuvant RT	1.00	Reference
Adjuvant RT alone	1.70	0.74–3.92
CLND alone	2.54	1.03–6.27
Observation	3.54	1.36–9.18
Sex		
Male	1.00	Reference
Female	0.75	0.42–1.34
Age		
<65	1.00	Reference
65–75 years	1.17	0.50–2.71
75–84 years	0.99	0.43–2.278
>85 years	1.98	0.75–5.25
Race		
White		
Other	1.47	0.49–4.42
Comorbidity		
0	1.00	Reference
1	1.22	0.65–2.30
≥1	1.36	0.54–3.44
Anatomic Site		
Head and neck	1.00	Reference
Upper limb and shoulder	0.42	0.19–0.91
Lower limb and hip	0.81	0.38–1.74
Trunk/other skin	0.46	0.18–1.15
T-classification		
T1	1.00	Reference
T2	1.09	0.61–1.95
T3-4	1.05	0.23–4.81
Nodes Positive		
1 LN metastasis		
2–3 LN metastases	1.82	0.98–3.39
4+ LN metastases	3.43	1.21–9.68
Margins		
Negative margins	1.00	Reference
Positive margins	1.14	0.50–2.62
Hospital Volume		
Lowest tercile		
Middle tercile	0.46	0.23–0.92
Highest tercile	0.46	0.23–0.92
Year of Diagnosis	1.10	0.63–1.91

Adjusted hazard ratio <1 indicates decreased hazard of mortality. Multivariate models were adjusted for confounding variables including age sex, comorbidities, anatomic site, T classification, positive margins, hospital type and year of diagnosis. Year of diagnosis over the study period is coded as a continuous variable reflecting the year in which the patient was diagnosed to account for changes in variables over time.
Abbreviations: SLNB = sentinel lymph node biopsy, CLND = completion lymph node dissection, HR = hazard ratio and CI = confidence interval.

offer a survival benefit and could be avoided.

Limitations

There are several limitations to consider when interpreting our results. First, as with all studies of large cancer registries there is the potential for errors in coding. Second, as patients are not randomly assigned to treatment, retrospective evaluation of treatment is prone to confounding by measured (i.e. age) and unmeasured variables. We attempted to control for confounding using multivariate Cox-proportional hazard models but residual confounding may persist. Although a randomized controlled trial would be ideal to investigate the role of both SLNB and CLND in MCC, one would be impractical given the rarity of this disease. Third, the NCDB does not collect information on regional recurrence, disease-specific survival or postoperative complications so we were unable to examine these outcomes. Forth, we were unable to examine if RT was applied to the primary, nodal basin or both. Finally, we were unable to examine the role of immunotherapy.

Conclusions

Our results show that in patients with SLN positive MCC, adjuvant RT or adjuvant RT and CLND conferred a survival benefit compared with CLND alone or observation. Based on these results we would recommend adjuvant RT for SLN positive MCC. We would recommend a personalized approach towards adding CLND to adjuvant RT based on patient age, comorbidities, lymph node basin to be dissected and burden of disease.

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The authors have no disclosures

Declaration of competing Interest

None

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