THE CHANGING ROLE OF COMPLETION LYMPHADENECTOMY IN MELANOMA

Matthew P. Doepker, MD
Assistant Professor of Surgical Oncology
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Palmetto Health USC MEDICAL GROUP

DISCLOSURES

- I have no financial disclosures

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GOALS

- Discuss the impact of completion lymph node dissection on survival and recurrence
- Discuss the potential downfalls of completion node dissection
- Discuss a role for a minimally invasive approach to completion lymph node dissection
- Discuss the emergence of adjuvant therapy

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ESTABLISHED IN 1812 FEBRUARY 13, 2014 VOL. 370 NO. 7

Final Trial Report of Sentinel-Node Biopsy versus Nodal Observation in Melanoma

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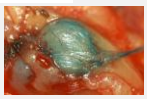
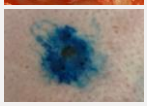
- Positive sentinel lymph node biopsy
  - Early removal of nodal metastasis results in at least an improvement in disease-free survival

No improvement in melanoma-specific survival

Demonstrated in intermediate thickness melanoma (1.2-3.5 mm)





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- MSLT-I demonstrated sentinel lymph node status to be the most important prognostic factor in patients with clinically node-negative disease

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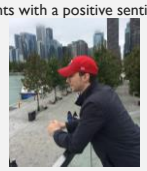
THE NEXT LOGICAL ???

- Does completion lymph node dissection extend survival in those patients with a positive sentinel lymph node biopsy?



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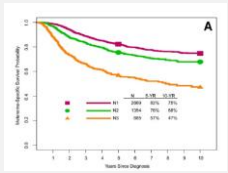
Melanoma Staging: Evidence-Based Changes in the American Joint Committee on Cancer Eighth Edition Cancer Staging Manual

Jeffrey E. Gershenwald, MD [1]; Richard A. Scolyer, MD [2,3]; Kenneth R. Hess, PhD [4]; Vernon K. Sondak, MD [5]; Georgina V. Long, MBBS, PhD [6]; Merrick I. Ross, MD [7]; Alexander J. Lazar, MD, PhD [8]; Mark B. Faries, MD [5]; John M. Kirkwood, MD [9]; Grant A. McArthur, MD, BS, PhD [1,]; Lauren E. Haydu, PhD [2,3]; Alexander M. M. Eggermont, MD, PhD [10]; Keith T. Flaherty, MD [11]; Charles M. Balch, MD [12]; John F. Thompson, MD [13]; for members of the American Joint Committee on Cancer Melanoma Expert Panel and the International Melanoma Database and Discovery Platform

- Melanoma Staging: AJCC 8th edition
  - Simplification of Stage III disease
  - The number of nodes needs to be determined to adequately stage the patient



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Increase in nodal burden leads to a worse survival

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Melanoma Patients with Positive Sentinel Nodes Who Did Not Undergo Completion Lymphadenectomy: A Multi-Institutional Study

Sandra L. Wong, MD,[1] Donald L. M
Jeffrey E. Gershenwald, MD,[4] Stanley P. J
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Journals of SURGICAL ONCOLOGY
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Observation After a Positive Sentinel Lymph Node Biopsy in Patients with Melanoma

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- Previous retrospective studies are consistent with the results published in MSLT-II

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- Previous retrospective studies are consistent with the results published in MSLT-II
- One other prospective trial also showed similar results

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Complete lymph node dissection versus no dissection in patients with sentinel lymph node biopsy positive melanoma (DeCOG-SLT): a multicentre, randomised, phase 3 trial

Ulrike Leiter*, Rudolf Stadler*, Cornelia Mauch, Werner Hohenberger, Norbert Brockmeyer, Carola Berking, Cord Sunderkötter, Martin Kaatz, Klaus-Werner Schulte, Percy Lehmann, Thomas Vogt, Jens Ulrich, Rudolf Herbst, Wolfgang Gehring, Jan-Christoph Simon, Ulrike Keim, Peter Martus, Claus Garbe, for the German Dermatologic Cooperative Oncology Group (DeCOG)

- DeCOG-SLT
  - Multicenter, randomized phase 3 trial
  - 483 agreed to random assignment
    - Observation (n = 233)
    - Completion lymph node dissection (n = 240)

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  - Multicenter, randomized phase 3 trial
  - 483 agreed to random assignment
    - Observation (n = 233)
    - Completion lymph node dissection (n=240)
  - Inclusion criteria

Cutaneous melanoma trunk, extremities
Breslow thickness ≥1 mm
Micrometastasis in SLN, including single cells

EXCLUDED
Head and neck
Regional macrometastasis

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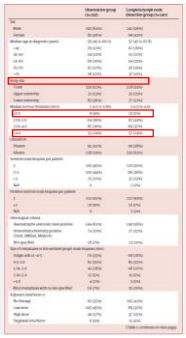

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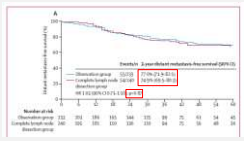
- Results
  - Median follow-up was 35 months
  - No significant difference in distant metastasis free-survival at 3 years between the two groups (p=0.87)



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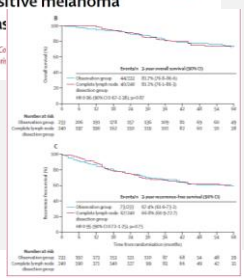
- Results
  - Median follow-up was 35 months
  - No significant difference in distant metastasis free-survival at 3 years between the two groups (p=0.87)
  - No significant difference was seen in overall survival or recurrence-free survival



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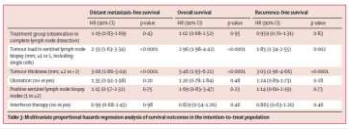

Significant predictors of distant metastasis-free survival
- Tumor load in SLNB
- Breslow thickness

Complete lymph node dissection versus observation showed NO significant effect on survival

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- Conclusion
  - Limitations → underpowered

Authors do not recommend CLND in patients with melanoma with lymph node metastasis of ≤ 1 mm

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Completion Dissection or Observation for Sentinel-Node Metastasis in Melanoma

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- MSLT-II
  - Multicenter, international randomized trial
  - 1939 patients underwent randomization into two groups
    - Observation
    - Completion node dissection

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- MSLT-II
  - Multicenter, international randomized trial
  - Per-protocol analysis
    - Observation (n = 824)
    - Dissection (n = 931)

Inclusion criteria:
- Age 18-75
- ECOG 0-1
- Tumor-positive SLN

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- Primary end point
  - Melanoma-specific survival
- Secondary end points
  - Nodal recurrence-free survival
  - Disease-free survival
  - Distant metastasis-free survival

Median follow-up – 43 months

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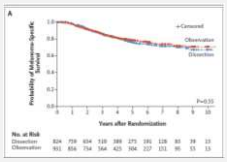

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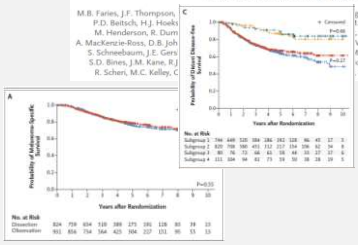

No significant difference in melanoma-specific survival or distant metastasis-free survival at 3 years

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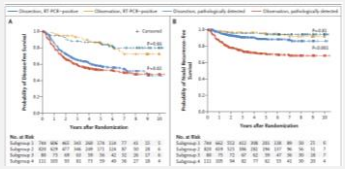
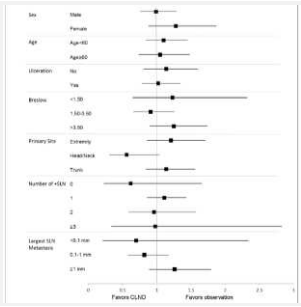


At 3 years
- DFS and nodal RFS are higher in the dissection group (p=0.02, p<0.001, respectively)



Subgroup analysis

Did not reveal any tumor or sentinel node characteristic that would help determine which subgroup of patients would benefit from completion lymph node dissection

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Completion Dissection or Observation for Sentinel-Node Metastasis in Melanoma

Table 2. Hazard Ratios for Melanoma-Related Death, According to Multivariable Prognostic Factors.*

Prognostic Factor	Dissection		Observation	
	Hazard Ratio (95% CI)	P Value	Hazard Ratio (95% CI)	P Value
Sex: male vs. female	1.13 (0.80–1.59)	0.50	1.41 (0.98–2.05)	0.07
Age, per 1-yr increase	1.00 (0.99–1.01)	0.93	1.01 (0.99–1.02)	0.15
Tumor thickness				
<1.50 mm†	1.00		1.00	
1.50–3.50 mm	1.64 (0.96–2.79)	0.07	2.46 (1.34–4.53)	0.004
>3.50 mm	3.82 (2.19–6.66)	<0.001	4.32 (2.31–8.08)	<0.001
Ulceration: present vs. absent	1.97 (1.40–2.77)	<0.001	2.17 (1.55–3.05)	<0.001
Site of melanoma				
Arm or leg‡	1.00		1.00	
Head or neck	0.81 (0.44–1.48)	0.49	1.40 (0.96–2.66)	0.07
Trunk	1.26 (0.89–1.77)	0.19	1.05 (0.74–1.49)	0.80
No. of positive sentinel nodes				
1‡	1.00		1.00	
2	1.08 (0.71–1.62)	0.73	1.27 (0.87–1.84)	0.21
≥3	1.37 (0.61–3.24)	0.64	2.01 (0.82–4.95)	0.13
Nonsentinel nodes: positive vs. negative	1.78 (1.19–2.67)	0.005	NA	

Multivariate Analysis
- Impact of prognosis of the Non-SLN
- Number of positive SLN's was not a significant prognostic factor

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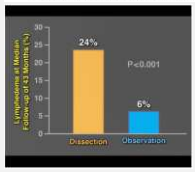

Adverse event-lymphedema
At follow-up of 43 months
- Observation Group-6%
- Dissection group-24%

P<0.001

Mild-64% Moderate-33% Severe-3%

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- MSLT-II demonstrated the prognostic significance of the nonsentinel-node status in those with a positive sentinel node disease

NO SURVIVAL BENEFIT But….

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Completion Dissection or Observation for Sentinel-Node Metastasis in Melanoma

M.B. Faries, J.F. Thompson, A.J. Cochran, R.H. Andtbacka, N. Mozzillo, J.S. Zager, T. Jahkola, T.L. Bowles, A. Testori, P.D. Beitsch, H.J. Hoekstra, M. Moncrieff, C. Ingvar, M.W.J.M. Wouters, M.S. Sabel, E.A. Levine, D. Agnese, M. Henderson, R. Dummer, C.R. Rossi, R.I. Neves, S.D. Trocha, F. Wright, D.R. Byrd, M. Matter, E. Hsueh, A. MacKenzie-Ross, D.B. Johnson, P. Terheyden, A.C. Berger, T.L. Huston, J.D. Wayne, B.M. Smithers, H.B. Neuman, S. Schneebaum, J.E. Gershenwald, C.E. Ariyan, D.C. Desai, L. Jacobs, K.M. McMasters, A. Gesierich, P. Hersey, S.D. Bines, J.M. Kane, R.J. Barth, G. McKinnon, J.M. Farma, E. Schultz, S. Vidal-Sicart, R.A. Hoefer, J.M. Lewis, R. Scheri, M.C. Kelley, O.E. Nieweg, R.D. Noyes, D.S.B. Hoon, H.-J. Wang, D.A. Elashoff, and R.M. Elashoff

- MSLT-II demonstrated the prognostic significance of the nonsentinel-node status in those with a positive sentinel node disease

NO SURVIVAL BENEFIT But….

Staging and regional disease control

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Will minimally invasive surgery help solve the puzzle?

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Safety and Feasibility of Minimally Invasive Inguinal Lymph Node Dissection in Patients With Melanoma (SAFE-MILND): Report of a Prospective Multi-institutional Trial

Jakub, James W. MD; Terando, Alicia M. MD; Samak, Amod MD; Ariyan, Charlotte E. MD; Faries, Mark B. MD; Zani, Babino Jr. MD; Neuman, Heather B. MD, MS, FACS; Wasif, Nabil MD; Farma, Jeffrey M. MD, FACS; Avetbook, Bruce J. MD; Billmoria, Karl Y. MD, MS; Grotz, Travis E. MD; Allred, Jacob B. (Jake); Suman, Vera J. PhD; Brady, Mary Sue MD, FACS; Tyler, Douglas MD; Wayne, Jeffrey D. MD; Nelson, Heidi MD

- SAFE-MILD trial
  - Prospective, multi-institutional
  - 87 had a MILD (88.5% were completed)

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- SAFE-MILD trial

Complications	Maximum Grade Complications (N = 87)			
	Grade 1	Grade 2	Grade 3	Total
Lymphedema	18 (21%)	26 (30%)	3 (3%)	47 (54%)
Wound infection	1 (1%)	9 (10%)	10 (11%)	20 (23%)
Hemorrhage	10 (11%)	2 (2%)	1 (1%)	13 (15%)
Seroma	3 (3%)	3 (3%)	6 (7%)	12 (14%)
Skin injury/necrosis	1 (1%)		2 (2%)	3 (3%)
Wound dehiscence	1 (1%)	1 (1%)		2 (2%)
Peripheral motor neuropathy			1 (1%)	1 (1%)
Other	2 (2%)	1 (1%)		3 (3%)
Total	37 (43%)	42 (49%)	23 (26%)	

41% of patients experienced lymphedema within 30 days of surgery
- Grade 1-17%
- Grade 2-22%
- Grade 3-2%

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- SAFE-MILD trial
  - Risk of short-term morbidity is decreased

What effect will a minimally invasive approach have on long-term lymphedema??

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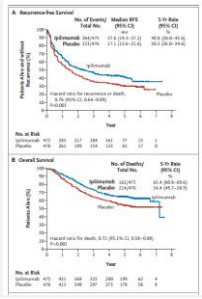
ORIGINAL ARTICLE

Prolonged Survival in Stage III Melanoma with Ipilimumab Adjuvant Therapy

A.M.M. Eggermont, V. Chiarion-Sileni, J.-J. Grob, R. Dummer, J.D. Wolchok, H. Schmidt, O. Hamid, C. Robert, P.A. Ascierto, J.M. Richards, C. Lebbé, V. Ferraresi, M. Smylie, J.S. Weber, M. Maio, L. Bastholt, L. Mortier, L. Thomas, S. Tahir, A. Hauschild, J.C. Hassel, F.S. Hodi, C. Taitt, V. de Pril, G. de Schaetzen, S. Suciu, and A. Testori



- Emergence of adjuvant therapy with a proven benefit in survival
- Risk-benefit regarding adverse events

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ORIGINAL ARTICLE

Adjuvant Nivolumab versus Ipilimumab in Resected Stage III or IV Melanoma

J. Weber, M. Mandala, M. Del Vecchio, H.J. Gogas, A.M. Arance, C.L. Cowey, S. Dalle, M. Schenker, V. Chiarion-Sileni, I. Marquez-Rodas, J.-J. Grob, M.O. Butler, M.R. Middleton, M. Maio, V. Atkinson, P. Queirolo, R. Gonzalez, R.R. Kudchadkar, M. Smylie, N. Meyer, L. Mortier, M.B. Atkins, G.V. Long, S. Bhatia, C. Lebbé, P. Rutkowski, K. Yokota, N. Yamazaki, T.M. Kim, V. de Pril, J. Sabater, A. Qureshi, J. Larkin, and P.A. Ascierto, for the CheckMate 238 Collaborators*

The NEW ENGLAND JOURNAL of MEDICINE

NOVEMBER 9, 2017

Adjuvant Dabrafenib plus Trametinib in Stage III BRAF-Mutated Melanoma

G.V. Long, A. Hauschild, M. Santinami, V. Atkinson, M. Mandalà, V. Chiarion-Sileni, J. Larkin, M. Nyakas, C. Dutriaux, A. Haydon, C. Robert, L. Mortier, J. Schachter, D. Schadendorf, T. Lesimple, R. Plummer, R.-J. P. Zhang, B. Moskovjev, J. Legos, K. Kefford, E. Dummer, and J.M. Kirkwood

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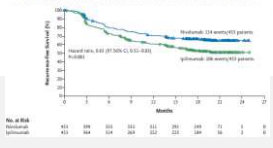
ORIGINAL ARTICLE

Adjuvant Nivolumab versus Ipilimumab in Resected Stage III or IV Melanoma



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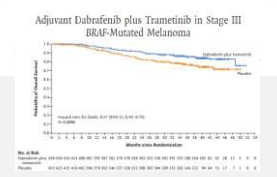

- Significant survival benefit in recurrence-free or overall survival
- 97% experienced adverse events
- Financial cost?

All patients in these trials underwent a completion lymph node dissection

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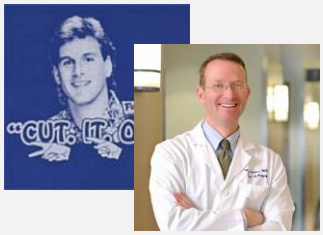

"Stop To Learn"

QUESTIONS????