25th Multidisciplinary Management of Cancers: A Case-based Approach

Melanoma Case Discussion

Friday, March 7, 2025

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24th Multidisciplinary Management of Cancers: A Case-based Approach

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Panelists

- Pauline Funchain, MD, Chair
- Tabitha Ting, MD, PhD, Fellow, Case Presenter

Medical Oncology
- Scott Christensen, MD, *UC Davis*
- Adil Daud, MD, *UCSF*
- Juraj Kavecansky, MD, *Kaiser*
- Kevin Kim, MD, *San Francisco Hematology and Oncology Associates*
- Tianhong Li, MD, *UC Davis*
- Katy Tsai, MD, *UCSF*

Dermatology
-Susan Swetter, MD, *Stanford*

Pathology
-Ryanne Brown, MD, *Stanford*

Surgical Oncology
- Robert Canter, MD, *UC Davis*
- Amanda Kirane, MD, PhD *Stanford*

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Disclosures

Faculty Name	Role	Type of Financial Relationship	Company
Pauline Funchain	**Chair**	Consultant	BMS, Merck, GigaGen, Eisai, Novartis, Array, Hexal AG, Replimune, Immunocore and Sanofi
		Grants/Research Support	Dr. Funchain reports research grants to her current and former institutions from Ideaya,BMS, Pfizer and Taiho Oncology
Tabitha Ting	**Fellow**	Disclosed no relevant financial relationships.	
Ryanne Brown	Panelist	Disclosed no relevant financial relationships.	
Robert Canter	Panelist	Advisory Board or Panel	Replimune
		Stock/Shareholder (excluding diversified mutual funds)	Abbvie Inc Com, Abbott Labs Com, Astrazeneca Plc Sponsored Adr, Bristol-Myers Squibb Co Com, Johnson & Johnson Com, and Pfizer Inc Com.
Adil Daud	Panelist	Advisory Board or Panel	Genoptix; GlaxoSmithKline; Caris, Eisai, and GLG
		Consultant	Genoptix, GlaxoSmithKline, Oncosec, Caris, Eisai, and GLG
		Grants/Research Support	Bristol-Myers Squibb; Checkmate Pharmaceuticals; Checkmate Pharmaceuticals; Genentech/Roche (Inst); GlaxoSmithKline (Inst); Incyte; Merck/Schering
		Stock/Shareholder (excluding diversified mutual funds)	Neuvogen; Trex bio
Juraj Kavecansky	Panelist	Disclosed no relevant financial relationships.	

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Disclosures

Kevin Kim	Panelist	Advisory Board or Panel Speaker's Bureau Grants/Research Support	BMS, Merck Eisai, Regeneron, and Pfizer Bristol Myer Squibbs Bristol Myer Squibbs,, Merck, ImmunoCore, Iovance, Moderna, Ideaya, Regeneron, Summit, and Replimmune.
Amanda Kirane	Panelist	Consultant	Expert speaker/ panelist for Iovance- February, March 2024 and Surgical consultant - replimune August 2024, Iovance October 2024.
Tianhong Li	Panelist	Advisory Board or Panel Grants/Research Support	Bristol Myers Squibb (BMS) AbbVie, Amgen, Astellas, AstraZeneca, Bristol Myers Squibb (BMS), Chugai Pharma, Duality Biologics, Genentech/LaRoche, Jounce Therapeutics, LabyRx, Immuno-Oncology, Merck, OncoC4/BioNTech, Novartis, RasCal Therapeutics, Tempus, and Xilio Therapeutics.
Susan Swetter	Panelist	Disclosed no relevant financial relationships.	
Katy Tsai	Panelist	Advisory Board or Panel Grants/Research Support	BMS Institutional research support: ABM Therapeutics, AstraZeneca, BioAtla, BMS, Genentech, Georgiamune, Ideaya Biosciences, Innovent, Oncosec, OnKure, Pfizer, Regeneron, and Replimune.

ANCO and i3 Health have mitigated all relevant financial relationships.

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25th Multidisciplinary Management of Cancers: A Case-based Approach

Outline

1. Case 1 – Neoadjuvant therapy
2. Case 2 – Stage II disease
3. Case 3 – TIL

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Case 1 - HPI

- 54yo M who presented in 6/2024 with a bleeding skin lesion on his upper back
- 7/2024: Underwent shave biopsy c/w invasive melanoma, nodular type, Breslow 7.0 mm, Mitoses: 12/mm2, ulceration+, margins+
- 9/19/24: Underwent WLE on upper left back lesion with positive SLNB (1/1 LN). FNA of the palpable axillary LN in wound bed also positive for melanoma. STAMP positive for BRAF V600E

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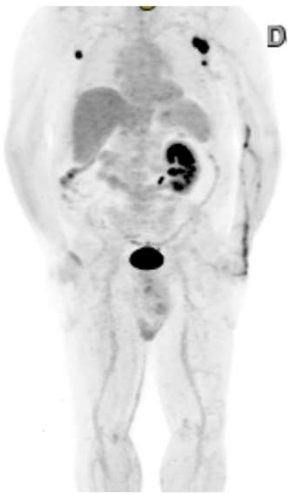
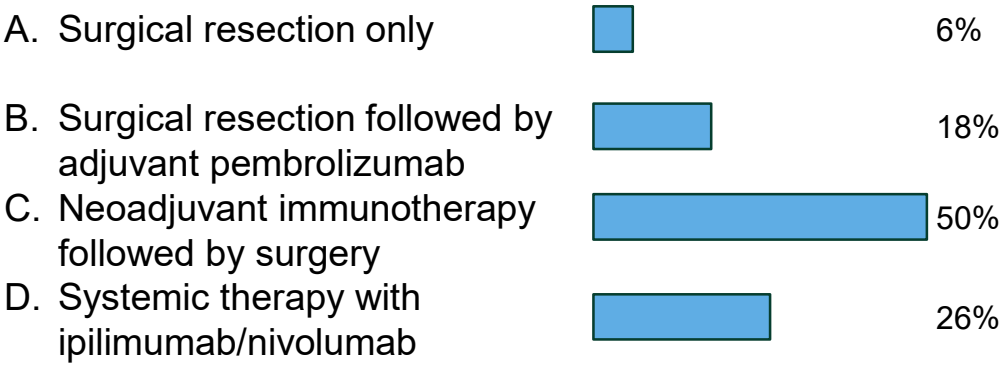
Case 1 - HPI

- 10/17/24 PET/CT - Bilateral axillary nodal metastases, L>R
- 10/18/24 MRI brain negative



Case 1 – Audience Question

What would you recommend for treatment?



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Case 1 - HPI

- 11/19/24: C1 neoadjuvant ipilimumab/nivolumab
- 12/10/24: C2 neoadjuvant ipilimumab/nivolumab

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Case 1 – Neoadjuvant therapy considerations

Pros

- Tumor shrinkage with potential for simpler or less extensive local therapy, or elimination of local therapy
- Early assessment of tumor biology allowing for dynamic decision making
- Elimination of micrometastases

Cons

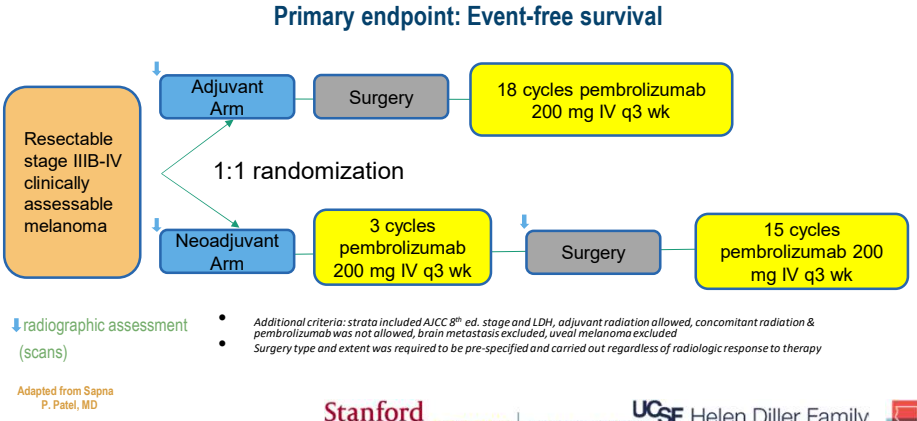
- Prolonged time prior to local treatment during which local disease can grow, or regional or distant disease develops
- Adverse effects that postpone a potentially curative procedure

Case 1 – Neoadjuvant treatment studies

Trial	Treatment Regimen	Key Findings	Reference
SWOG S1801	Neoadjuvant Pembrolizumab	Improved event-free survival rates compared to adjuvant pembrolizumab	*NEJM, 2023*
NADINA	Neoadjuvant Ipilimumab + Nivolumab	Improved event-free survival rates compared to adjuvant nivolumab	*NEJM, 2024*

Blank CU, et al. (2024). Neoadjuvant Nivolumab and Ipilimumab in Resectable Stage III Melanoma. *NEJM, 391*(18), 1696-1708.

Case 1 – S1801 Study Schema: Neoadjuvant vs adjuvant IO in cutaneous melanoma



Blank CU, et al. (2024). Neoadjuvant Nivolumab and Ipilimumab in Resectable Stage III Melanoma. *NEJM, 391*(18), 1696-1708.

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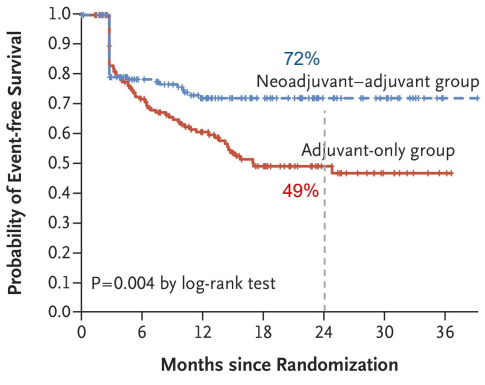
Case 1 – S1801 trial



No. at Risk

Neoadjuvant–adjuvant group	154	96	69	46	25	17	1
Adjuvant-only group	159	98	67	40	22	10	2

Patel SP et al. N Engl J Med 2023;388:813-823

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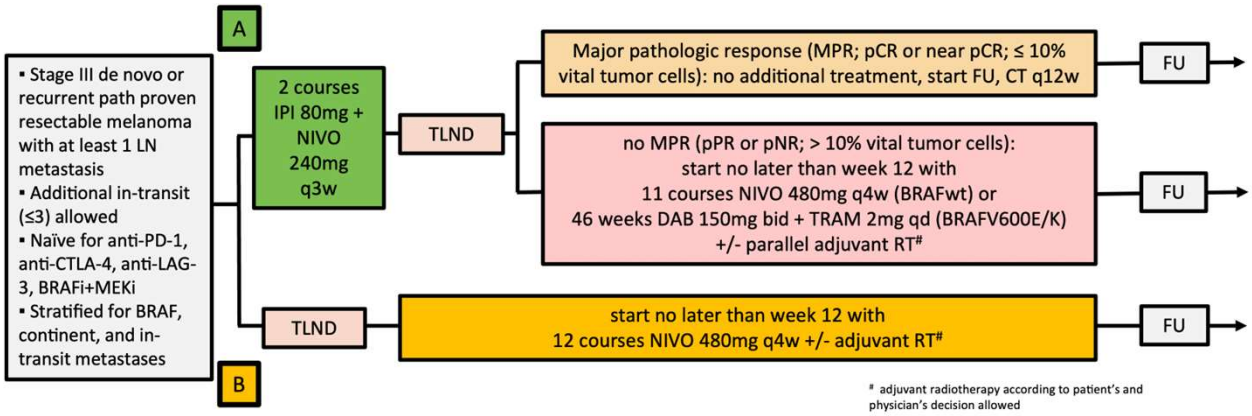
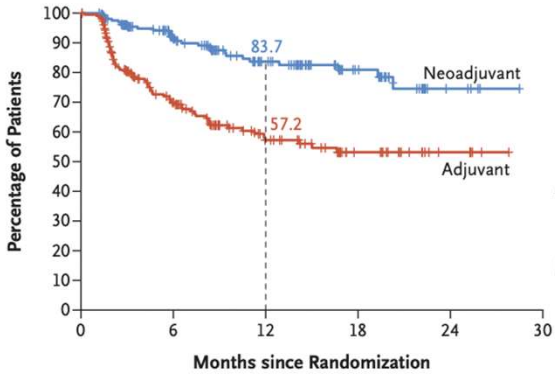
Case 1 – NADINA trial



Adapted from Christian U. Blank, MD PhD

Blank CU, et al. (2024). Neoadjuvant Nivolumab and Ipilimumab in Resectable Stage III Melanoma. *NEJM, 391*(18), 1696-1708.

Case 1 – Event-free survival in the NADINA trial



No. at Risk (no. censored)					
Neoadjuvant	212 (0)	126 (71)	77 (111)	34 (152)	5 (179)
Adjuvant	211 (0)	100 (57)	53 (89)	23 (116)	6 (133)

No. of Events/ Total No. of Patients	
Neoadjuvant	28/212
Adjuvant	72/211

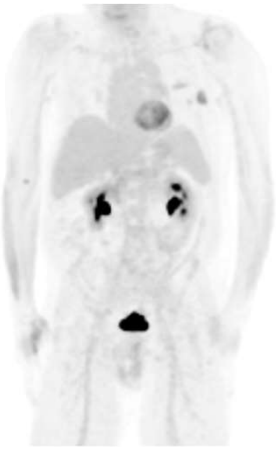
Adjusted difference in restricted mean survival time, 8.00 mo (99.9% CI, 4.94–11.05); P<0.001

Hazard ratio for progression, recurrence, or death, 0.32 (99.9% CI, 0.15–0.66)

Blank CU, et al. (2024). Neoadjuvant Nivolumab and Ipilimumab in Resectable Stage III Melanoma. *NEJM, 391*(18), 1696-1708.

Case 1 - HPI

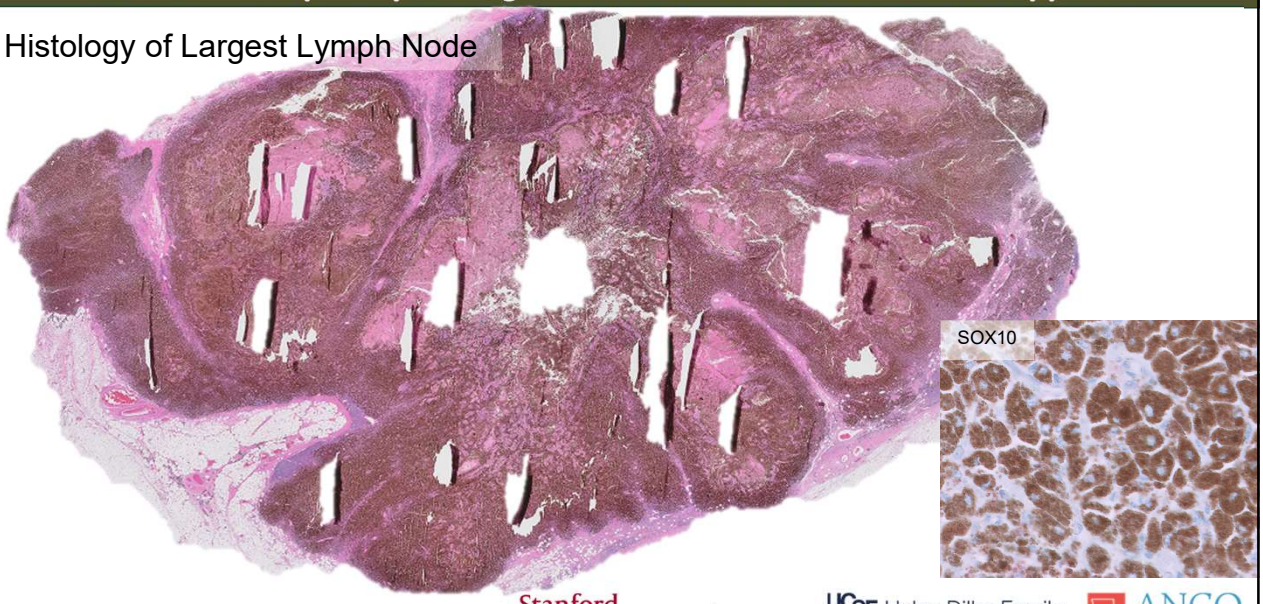
- 1/8/2025 PET/CT: Decreased size/activity of axillary lymph nodes
- 1/16/25: L axillary lymph node dissection
  - Fibrosis and nodular aggregates of pigmented macrophages and necrotic tumor consistent with melanoma (completely regressed with treatment effect), metastatic to 12/17 lymph nodes
  - Largest tumor deposit size: 3.3 cm
  - Location: Subcapsular and intraparenchymal
  - Extracapsular extension: Present



Case 1 – Panel Discussion

- What are surgical considerations when evaluating resectability before and after neoadjuvant treatment?
  - Is there utility to clipping the site of disease?
  - If there is a good response to neoadjuvant therapy, what are your criteria for determining whether resection is still indicated?
- What are considerations from the pathology perspective regarding the identification and processing of specimens related to neoadjuvant therapy?

Histology of Largest Lymph Node



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Case 1 – Panel Discussion

- Most adjuvant/neoadjuvant studies use EFS as a primary endpoint rather than OS. Do you think this is an appropriate endpoint?
- What are considerations when deciding between single agent versus combination therapy for neoadjuvant treatment?
- If a patient has a mixed response after initial neoadjuvant therapy, what are the next steps (e.g. continuing treatment, increasing to full dose ipi/nivo, or viewing as pseudoprogression)?

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Case 1 – Summary

- Neoadjuvant therapy carries benefits including the potential for less extensive local therapy and earlier treatment of micrometastases, but may carry the risk of loss of local control if surgery cannot be done after neoadjuvant therapy
- The NADINA and S1801 trials show improvement in EFS with neoadjuvant immunotherapy when compared to adjuvant immunotherapy

Case 2

Case 2 – HPI

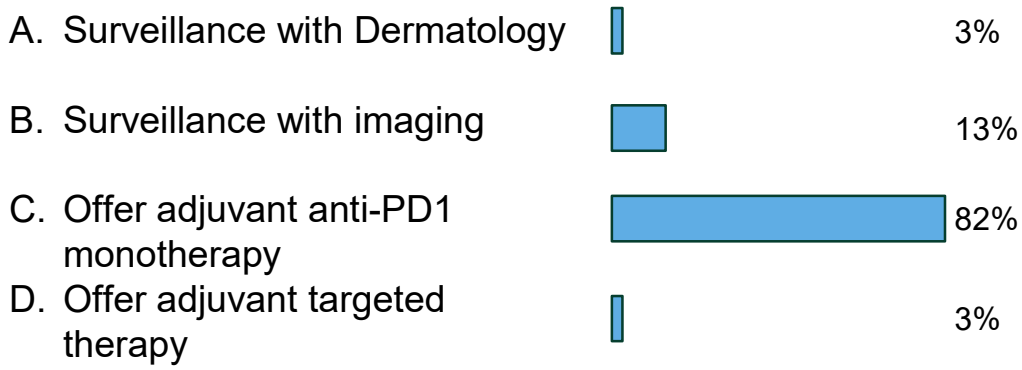
- 80yo M presented in 2/14/24 with a worsening skin lesion on his left chest
- 1/12/24 – Skin biopsy: Invasive melanoma, nodular type, Breslow at least 1.8 mm, Mitoses: 6/mm2, Ulceration present, positive peripheral and deep margins (outside hospital)
- 2/14/24 - Repeat biopsy at Stanford: Invasive melanoma, nodular type, Breslow at least 4.1 mm, Mitoses: 7/mm2, Ulceration absent, Positive peripheral and deep margins

Case 2 - HPI

- 3/14/24: Underwent WLE with updated Breslow of 8.0 mm and BRAF IHC neg. Attempted SLNB but lymph nodes did not map
- 4/16/24: PET/CT and MRI brain were negative for metastatic disease

Case 2 – Audience Question

What would you recommend for treatment?



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Case 2 – Panel Discussion

- What information do you want to know when deciding whether or not to pursue adjuvant therapy?
- What do you consider to be high risk factors that might lead you to opt for or against adjuvant therapy?
- How often would you recommend doing surveillance scans for a Stage II cutaneous melanoma patient?

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Case 2 - HPI

- 8/21/24 L axilla US: Suspicious 0.7 cm x 0.5 cm lymph node, s/p core biopsy c/ melanoma
- 9/17/24 PET: s/p L axillary LN biopsy with possible small ill-defined residual lymph node demonstrating faint uptake. No distant metastatic disease
- 10/1/24 L axillary image guided lymph node removal: One lymph node positive for metastatic melanoma by histology and immunohistochemistry (1/1)

Case 2 – Panel Discussion

- Now knowing that he had progression with nodal metastatic disease, would you have approached his initial treatment differently?
- What would you recommend now?

Case 2 - HPI

- 11/19/24 Started adjuvant pembrolizumab q6 weeks

Case 2 - HPI

- 12/31/24: Presented prior to C2 pembrolizumab with elevated troponin of 2112
  - EKG: No concern for MI
  - TTE: LVEF 29% iso known HFrEF. Decreased RVSP and larger RV compared to prior TTE in 2/2024
  - NT-proBNP 6,648 (previously 7,445 in 4/2024)
  - CK, CRP, ESR wnl

Case 2 – Panel Discussion

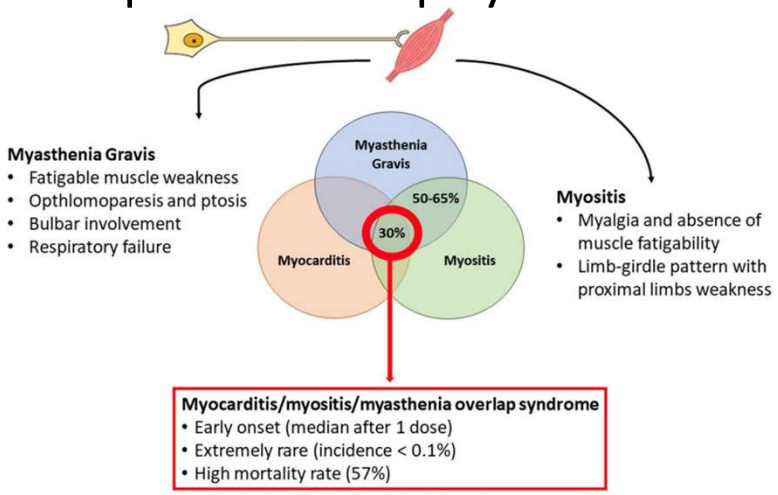
- What is your level of clinical concern for a possible irAE?
- What are your next steps for diagnostic workup?
- At what point do you start steroids if you suspect cardiotoxicity, and what is your approach to management?

Case 2 – ASCO guidelines for ICI cardiotoxicity

Grading	Management
G1: Abnormal cardiac biomarker testing without symptoms and with no ECG abnormalities	All grades warrant workup and intervention, given the potential for cardiac compromise. Hold ICPi for G1 elevated troponin[a] and recheck troponin 6 hours later. May consider resuming once normalized or if believed not to be related to ICPi. Hold ICPi and discontinue for ≥ G2. For patients with grade ≥ 2, early (ie, within 24 hours) initiation of high-dose corticosteroids (1-2 mg/kg/d of prednisone, oral or IV depending on symptoms) should be considered as it is likely to be beneficial without adverse effects. Admit patient for cardiology consultation. Management of cardiac symptoms according to ACC/AHA guidelines and with guidance from cardiology. Immediate transfer to a coronary care unit should be considered for patients with elevated troponin or conduction abnormalities. For new conduction delay, consider a pacemaker. In patients without an immediate response to high-dose corticosteroids, consider early institution of cardiac transplant rejection doses of corticosteroids (methylprednisolone 1 g every day) and the addition of either mycophenolate, infliximab, or antithymocyte globulin.[210] Consider abatacept (costimulatory molecule blockade) or alemtuzumab (CD52 blockade) as additional immunosuppression in life-threatening cases.[211,212]
G2: Abnormal cardiac biomarker testing with mild symptoms or new ECG abnormalities without conduction delay	
G3: Abnormal cardiac biomarker testing with either moderate symptoms or new conduction delay	
G4: Moderate to severe decompensation, IV medication or intervention required, life-threatening conditions	

Schneider BJ, et al. (2022). Cardiovascular Toxicity of Immune Checkpoint Inhibitors: A Guide for Clinicians. *J Clin Oncol.* 40(3):315.

Case 2 –Triple M overlap syndrome



Raschi E, et al. (2023). Cardiovascular Toxicity of Immune Checkpoint Inhibitors: A Guide for Clinicians. *Drug Saf*. 46(9):819-833.

Case 2 - HPI

- 12/31/24: Admitted due to concern for ICI-associated vs viral myocarditis in setting of recent URI (productive cough, rhinorrhea)
  - Infectious workup: Respiratory viral panel, HIV, hepatitis, quantiferon negative
  - Started on solumedrol 1g x 4, followed by pred taper

Case 2 – Summary

- The decision regarding whether to pursue adjuvant therapy in early stage disease is a multidisciplinary discussion involving surgery, pathology, and medical oncology
- Patients on immunotherapy should be closely monitored for irAEs; current ASCO guidelines provide helpful parameters for monitoring and managing irAEs
- Any case involving suspicion for myocarditis, myasthenia gravis, or myositis should include workup for the other "M" in triple M overlap syndrome

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Case 3

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Case 3 - HPI

54yo F presented in 2021 with palpable inguinal lymphadenopathy

- History of Stage IIA melanoma in 2015, treated by WLE and with negative SLNB
- 1/3/2022: Biopsy of left groin LN confirmed metastatic melanoma
  - BRAF wild-type
- 1/14/2022 CT CAP: 2.2cm left inguinal lymph node, no other evidence of metastatic disease

Case courtesy of Dr. Amanda Kirane

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Case 3 - HPI

- Enrolled in SWOG S1801 trial: Randomized to adjuvant arm, underwent ILND with single positive lymph node on 2/17/22
- 3/2022-11/2022: Continued with adjuvant pembrolizumab x 8 cycles
- 11/2022: Presented with cutaneous recurrence near inguinal incision
- 12/2022-4/2023: Underwent 8 cycles of TVEC + pembrolizumab

Case courtesy of Dr. Amanda Kirane

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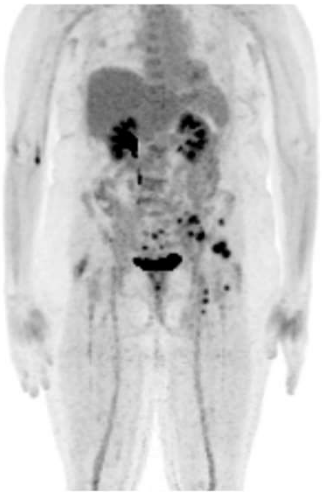
Case 3 - HPI

- 2/2023: CT revealed a 1.5 cm left external iliac node, confirmed to be melanoma on FNA
- 6/2023: Underwent left Iliac dissection
- 6/7/23-11/1/23: Adjuvant pembro x 7 cycles

Case courtesy of Dr. Amanda Kirane

Case 3 - HPI

- 10/2023: PET/CT showed new abdominal masses measuring up to 2.2 cm with subsequent 11/2023 FNA path consistent with melanoma
- 11/22/2023-1/24/2024: Ipi/Nivo x 4 cycles c/b irAE colitis and progression of disease on CT



Case courtesy of Dr. Amanda Kirane

Case 3 – Panel Discussion

- What is your next step in management?
- In what order of preference do you think about therapies for checkpoint-refractory melanoma?

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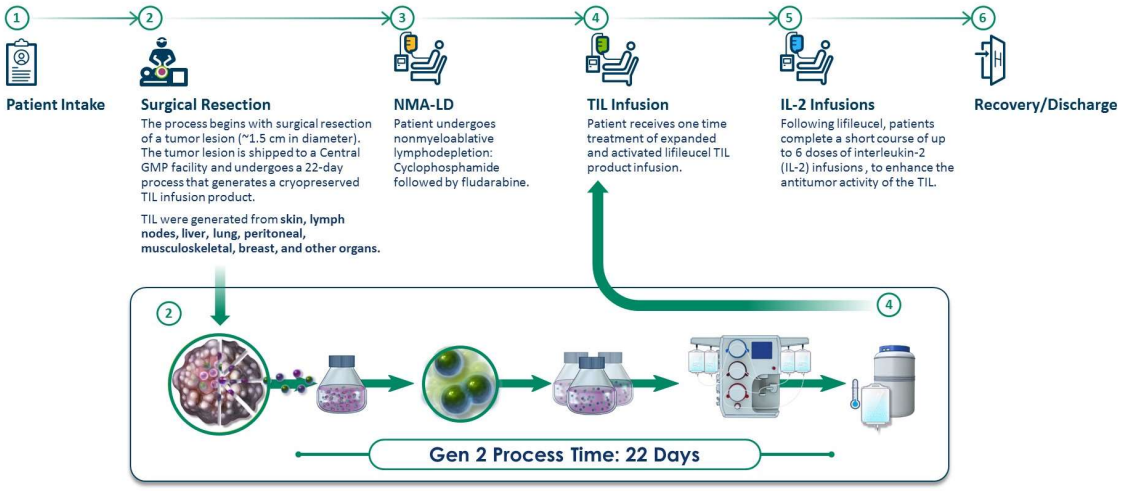
Case 3 – TIL overview



Courtesy of Amod Sarnaik, MD, H.Lee Moffitt Cancer Center, Tampa, FL.
Presented at 2020 ASCO.

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Case 3 – TIL trial (C-144-01) for PD-1 refractory melanoma

Patient Population

Unresectable or metastatic melanoma treated with ≥1 prior systemic therapy including a PD-1–blocking antibody and, if *BRAF* V600 mutation positive, a BRAF inhibitor ± MEK inhibitor

Cohort 1
Noncryopreserved TIL product (Gen 1)
n=30
Closed to enrollment

Cohort 2
Cryopreserved lifileucel (Gen 2)
n=66
Enrollment:
Apr 2017 to Jan 2019

Cohort 4
Cryopreserved lifileucel (Gen 2)
n=75*
Enrollment:
Feb 2019 to Dec 2019

Cohort 3
Lifileucel re-treatment
n≈10

Key Endpoints
- Primary: ORR (IRC-assessed using RECIST v1.1)
- Secondary: DOR, PFS, OS, TEAE incidence and severity

Key Eligibility Criteria
- ≥1 tumor lesion resectable for TIL generation (≥1.5 cm in diameter) and ≥1 target tumor lesion for response assessment
- Age ≥18 years at time of consent
- ECOG performance status 0–1
- No limit on number of prior therapies

Treatment Regimen
- Lifileucel, a cryopreserved TIL cell therapy product, was used in Cohorts 2 and 4 and manufactured using the same 22-day Gen 2 process
- All patients received NMA-LD, a single lifileucel infusion, and up to 6 doses of high-dose IL-2

Data cutoff date: 15 July 2022

Eligibility and treatment were identical for Cohorts 2 and 4

Slide courtesy of Dr. Allison Betof Warner
Sarnaik et al. SITC 2022

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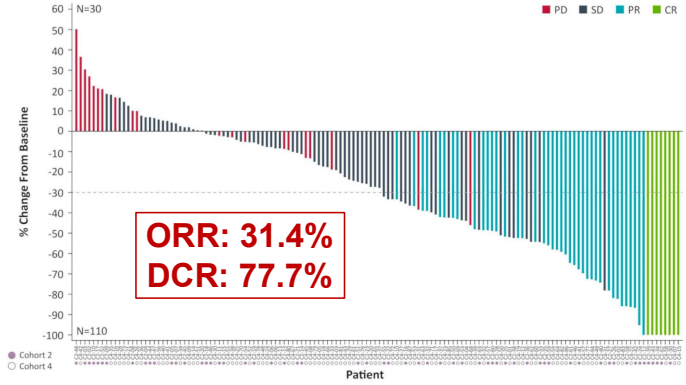
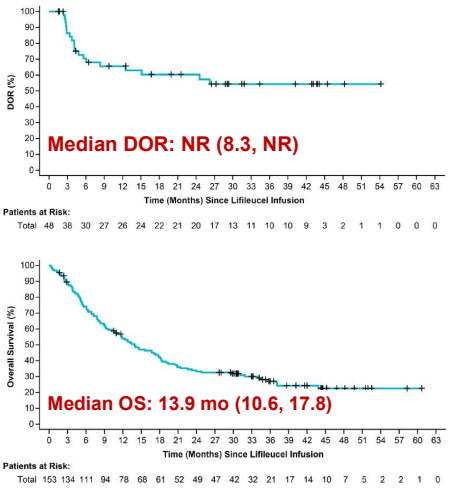
Case 3 – TIL trial for PD-1 refractory melanoma





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Chesney et al. SITC 2022

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The NEW ENGLAND JOURNAL of MEDICINE

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Tumor-Infiltrating Lymphocyte Therapy or Ipilimumab in Advanced Melanoma

M.W. Rohaan, T.H. Borch, J.H. van den Berg, Ö. Met, R. Kessels, M.H. Geukes Foppen, J. Stoltenborg Granhøj, B. Nuijen, C. Nijenhuis, I. Jedema, M. van Zon, S. Scheij, J.H. Beijnen, M. Hansen, C. Voermans, I.M. Noringriis, T.J. Monberg, R.B. Holmstroem, L.D.V. Wever, M. van Dijk, L.G. Grijpink-Ongering, L.H.M. Valkenet, A. Torres Acosta, M. Karger, J.S.W. Borgers, R.M.T. ten Ham, V.P. Retèl, W.H. van Harten, F. Lalezari, H. van Tinteren, A.A.M. van der Veldt, G.A.P. Hospers, M.A.M. Stevense-den Boer, K.P.M. Suijkerbuijk, M.J.B. Aarts, D. Piersma, A.J.M. van den Eertwegh, J.-W.B. de Groot, G. Vreugdenhil, E. Kapiteijn, M.J. Boers-Sonderen, W.E. Fiets, F.W.P.J. van den Berkmortel, E. Ellebaek, L.R. Hölmich, A.C.J. van Akkooi, W.J. van Houdt, M.W.J.M. Wouters, J.V. van Thienen, C.U. Blank, A. Meerveld-Eggink, S. Klobuch, S. Wilgenhof, T.N. Schumacher, M. Donia, I.M. Svane, and J.B.A.G. Haanen

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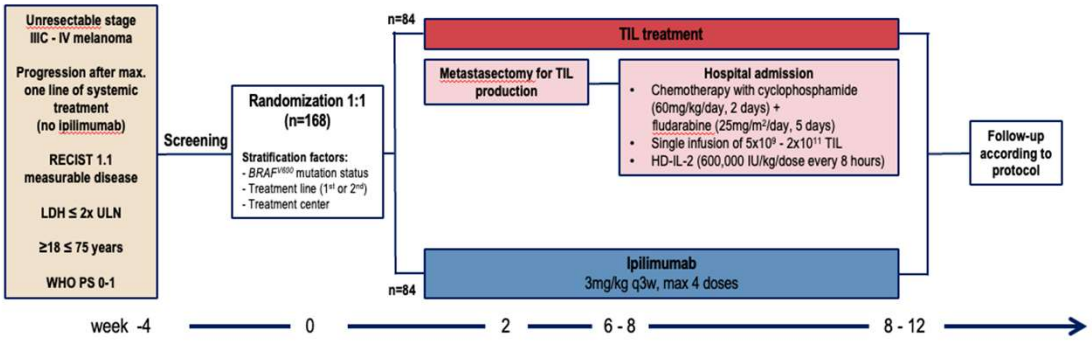
Case 3 – TIL Clinical Trial



Primary endpoint: Progression-free survival (PFS) according to RECIST 1.1 per investigator review in the intention-to-treat population (ITT)*

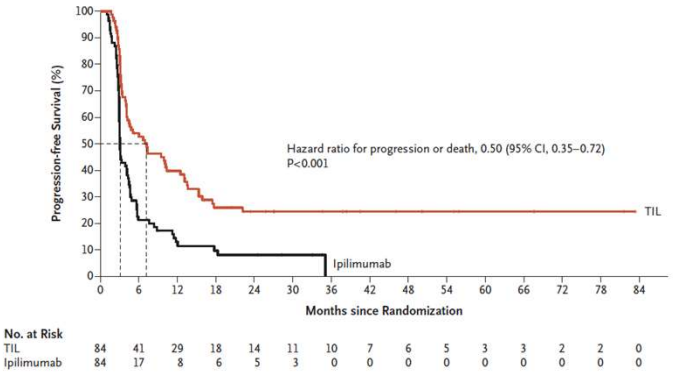
*Using the stratified (unweighted) log-rank test and the stratified cox regression model. The study was considered to be positive when PFS after TIL is significantly longer than ipilimumab, based on the log-rank test with a two-sided p-value below 0.05.

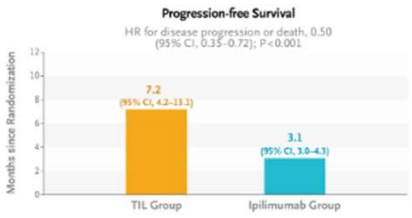
Slide Courtesy of Dr. Allison Betof-Warner
Rohaan et al. NEJM 2022

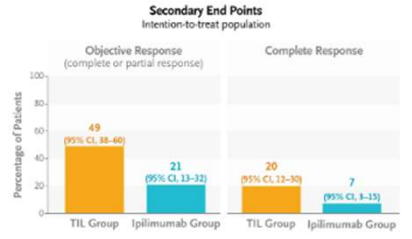
24th Multidisciplinary Management of Cancers: A Case-Based Approach

Case 3 – TIL Clinical Trial

Progression-Free Survival







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Case 3 – Real world TIL eligibility

- Inclusion criteria:
  - Unresectable stage IIIC or IV melanoma that progressed after standard therapies; ECOG status of 0 or 1, adequate organ function (hematologic, hepatic, renal), at least one resectable lesion over 1.5 cm
- Exclusion criteria:
  - Active systemic infection, autoimmune disease, significant cardiovascular condition, concurrent malignancies, pregnancy, active/symptomatic brain metastases, high dose steroids, age < 75 yo

Case 3 – Panel Discussion

- What are surgical criteria for obtaining viable TIL samples?
  Would you consider expanding the current TIL eligibility criteria?
- What are pathologic considerations in harvesting and analyzing TIL samples?

Case 3 – Panel Discussion

- What are oncologic criteria that should be used to determine TIL eligibility?
- Should patients who have irAEs receive TIL therapy?
- Do you use bridging therapy while waiting for TIL production, and if so, what bridging options would you consider, or avoid?

Case 3 - HPI

- 4/12/24: Underwent TIL harvest
- 5/22/24: Completed palliative radiation to left thigh, 20 Gy post-resection
- 5/2024 CT CAP: Disease progression with new and enlarging proximal left lower extremity and abdominal wall intramuscular metastases
- 7/2024: Repeat TIL harvest as prior sample was out of spec. Received palliative radiation to abdominal/inguinal masses

Case courtesy of Dr. Amanda Kirane

Case 3 - HPI

- 7/11/24: Received single dose of nivolumab/relatlimab as bridging therapy
- 8/16 - 9/02/24: Received TIL
- 12/2/24: PET/CT and MRI brain showed complete response (12 weeks after TIL)

Case courtesy of Dr. Amanda Kirane

Case 3 – Panel discussion

- Should TIL be offered earlier in the disease course when patients have a higher performance status, or is it better reserved as an option after multiple lines of therapy have failed?

Case courtesy of Dr. Amanda Kirane

Case 3 – Summary

- TIL is an emerging therapy option for checkpoint inhibitor-refractory advanced melanoma that offers superior response rates compared to other treatment strategies including immunotherapy
- There are multiple considerations for TIL candidacy including accessibility of resectable tumor tissue, age, performance status, brain metastases.

Thank You!