Mycosis Fungoides & Sezary Syndrome

Current Practice and Future Directions

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Outline

- Introduction
- Classification of Cutaneous T-Cell NHL
- Diagnosis & differential diagnosis
- Principles of Management
- Advances in detection of malignant population
- Cell of origin

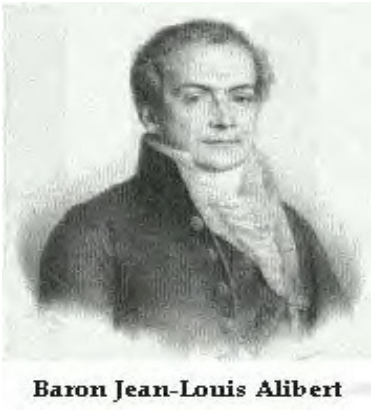
Mycosis Fungoides & Sézary Syndrome

Courtesy of Prof L. Cerroni (Univ of Gratz)

1806: Mycosis fungoides

French Dermatologist Dr. Alibert

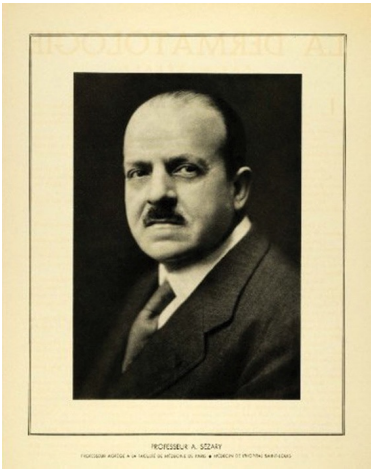
"Mushroom – like fungal disease"



Baron Jean-Louis Alibert

1938: Sezary syndrome

Sézary & Bouvrain



1972: Sezary syndrome:
T-cell derived disease

WHO Revised 4th Ed.	WHO 5th Ed.	ICC
Primary cutaneous CD4+ small/medium T-cell lymphoproliferative disorder	Primary cutaneous CD4-positive small or medium T-cell lymphoproliferative disorder (PCSM-LPD)	Primary cutaneous small/medium CD4+ T-cell lymphoproliferative disorder
Primary cutaneous acral CD8-T-cell lymphoma	**Primary cutaneous acral CD8-positive lymphoproliferative disorder** [1]	**Primary cutaneous acral CD8-positive lymphoproliferative disorder** [1]
Mycosis fungoides	Mycosis fungoides (MF)	Mycosis fungoides
Primary cutaneous CD30-positive T-cell lymphoproliferative disorder: Lymphomatoid papulosis	Primary cutaneous CD30-positive T-cell lymphoproliferative disorder: Lymphomatoid papulosis (LyP) • Primary mucosal CD30-positive T-cell lymphoproliferative disorder • LyP – A, B, C, D, E • LyP with DUSP22 locus rearrangement	Primary cutaneous CD30-positive T-cell lymphoproliferative disorder: Lymphomatoid papulosis
Primary cutaneous CD30-positive T-cell lymphoproliferative disorder: Primary cutaneous anaplastic large cell lymphoma	Primary cutaneous CD30-positive T-cell lymphoproliferative disorder: Primary cutaneous anaplastic large cell lymphoma (C-ALCL)	Primary cutaneous CD30-positive T-cell lymphoproliferative disorder: Primary cutaneous anaplastic large cell lymphoma
Subcutaneous panniculitis-like T-cell lymphoma	Subcutaneous panniculitis-like T-cell lymphoma (SPTCL)	Subcutaneous panniculitis-like T-cell lymphoma
Primary cutaneous gamma/delta T-cell lymphoma	Primary cutaneous gamma/delta T-cell lymphoma (PCGD-TCL)	Primary cutaneous gamma/delta T-cell lymphoma
Primary cutaneous CD8-positive aggressive epidermotropic cytotoxic T-cell lymphoma	Primary cutaneous CD8-positive aggressive epidermotropic cytotoxic T-cell lymphoma (PCAETL)	Primary cutaneous CD8-positive aggressive epidermotropic cytotoxic T-cell lymphoma
Not included	**Primary cutaneous peripheral T-cell lymphoma, NOS (pcPTCL-NOS)** [2]	Not included

Sezary syndrome = T cell leukemia

CTCL Subtypes Based on Clinical Behavior

INDOLENT	AGGRESSIVE	VERY AGGRESSIVE
Mycosis fungoides	*Sezary syndrome*	*Primary cutaneous CD8+ aggressive epidermotropic cytotoxic T-cell lymphoma*
Lymphomatoid papulosis	*Subcutaneous panniculitis-like T-cell lymphoma (HLH)*	*Primary cutaneous g/d T-cell lymphoma*
Primary cutaneous anaplastic large cell lymphoma		*Primary cutaneous PTCL, NOS*
Primary cutaneous CD4+ small/medium pleomorphic T-cell LPD		
Primary cutaneous acral CD8+ T-cell LPD		

Mycosis Fungoides & Sezary Syndrome

Median age: 63 years AA 53 years

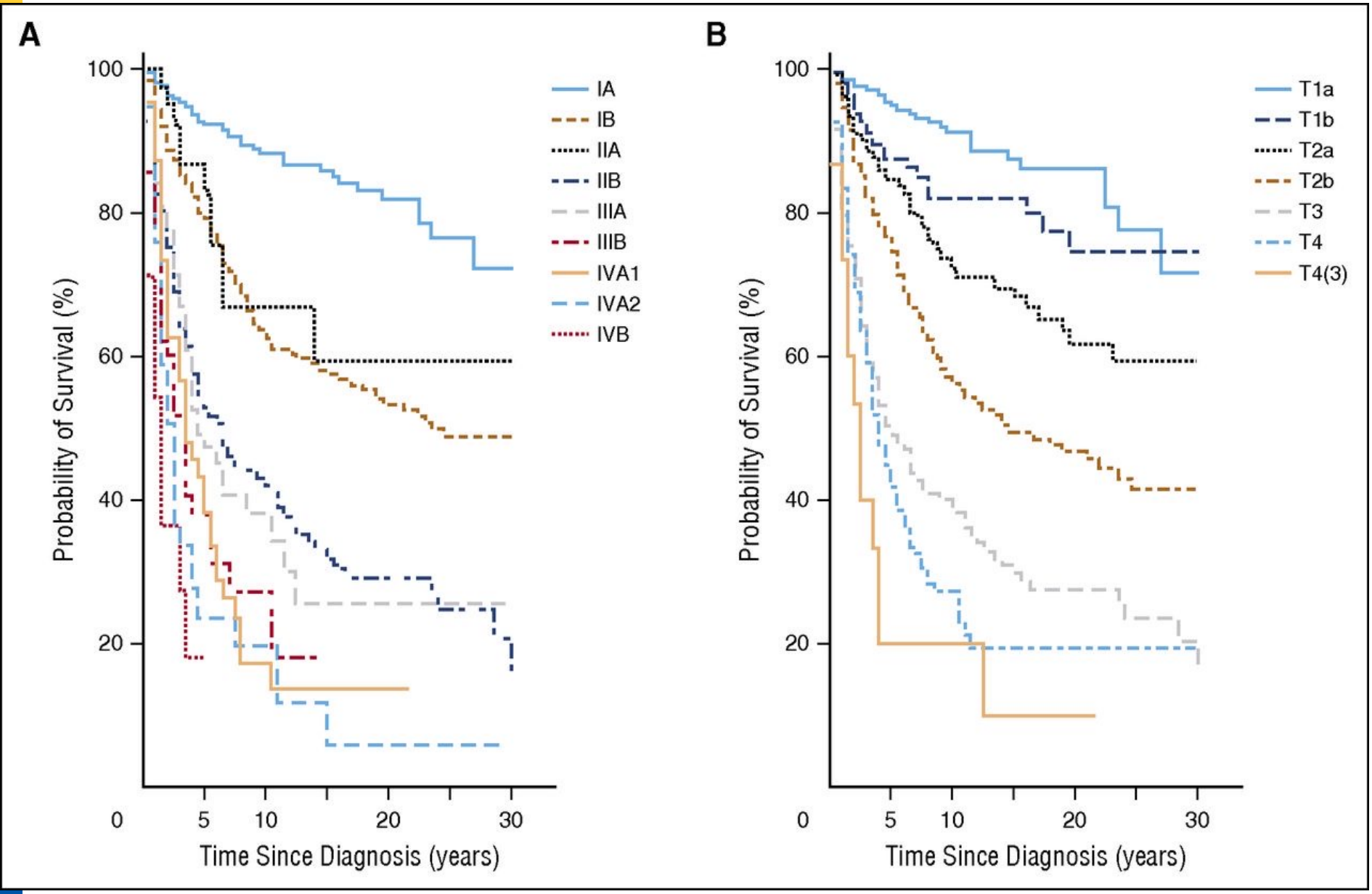
Incidence - MF: 0.55/100, 000, SS: 0.01/100, 000 (SEER)
1,600 pts/year/USA

MF 50%, SS 2.5% of CTCL

Early stage (I-IIA): OS >25 years
Advanced stage (IIB-IVB): OS 1.5 year

No curative therapy except alloBMT

Prognosis of Mycosis Fungoides and Sézary Syndrome



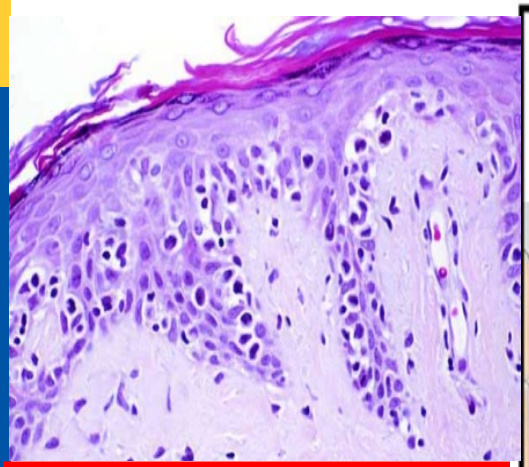
Whittaker S et al., Blood, 2016

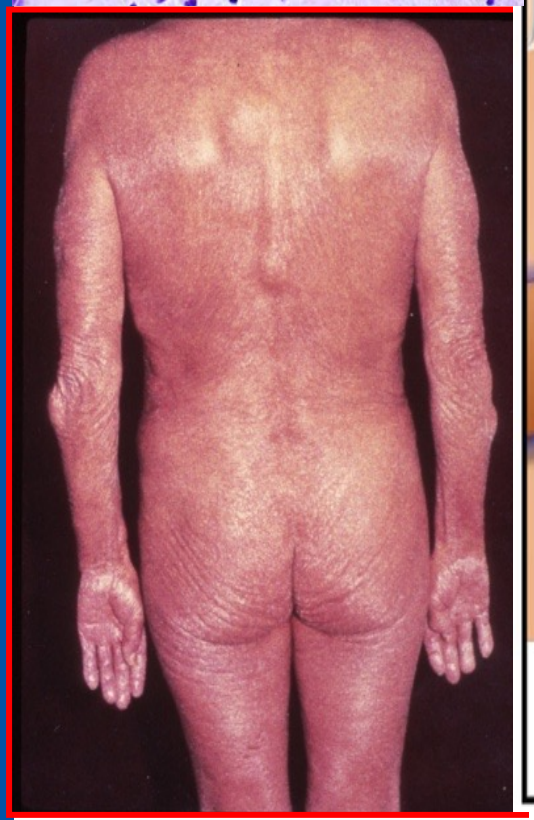
Diagnosis & Differential Diagnosis

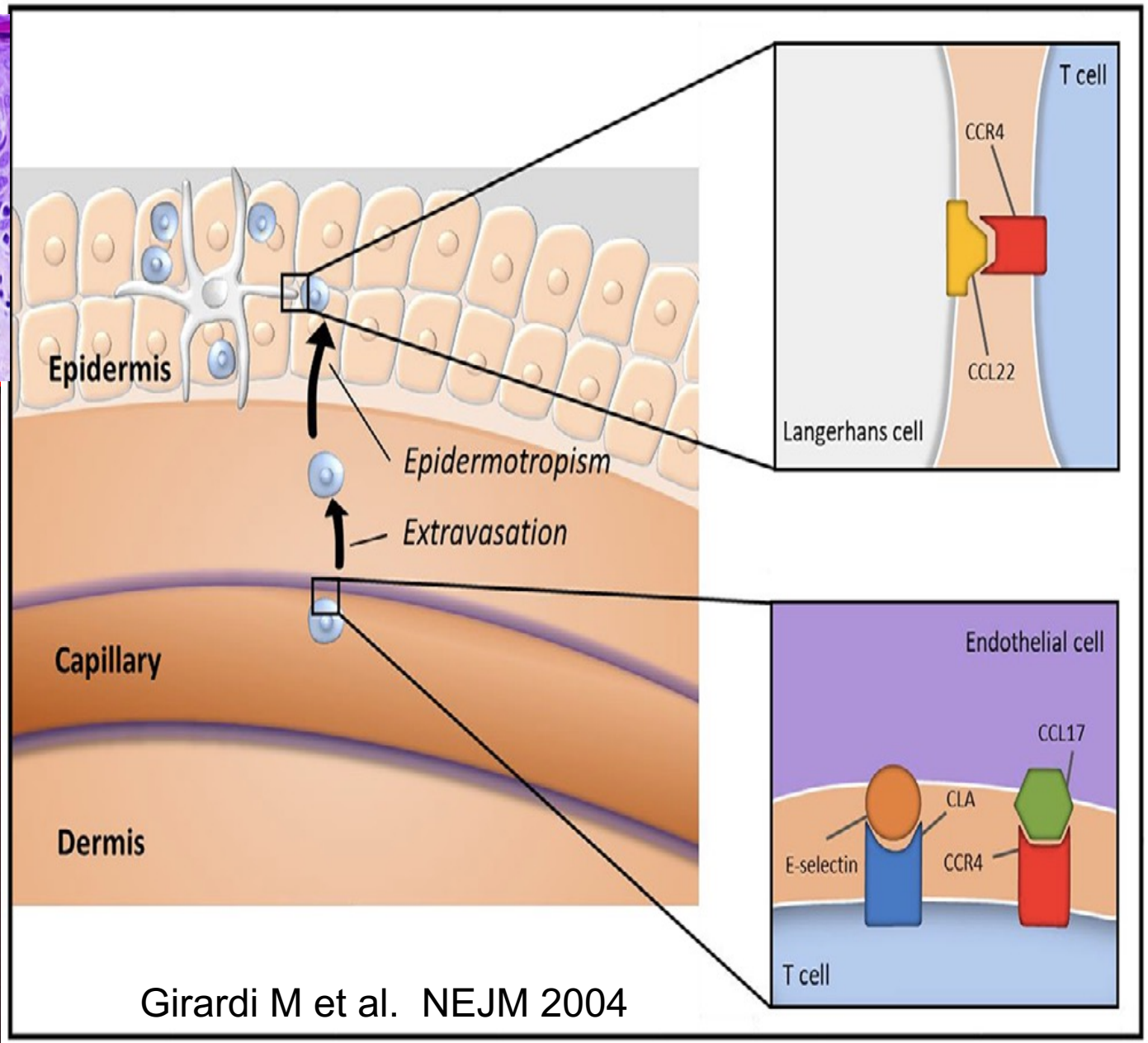
Sezary Syndrome
Clinical manifestation

- Prodromic phase: patches, plaques before erythroderma
- 86% of pts develop erythroderma during course of disease
- 50% of pts have non-specific dermatitis on initial biopsy
- Advanced stage: tumors, hyperleukocytosis, large cell transformation

Mycosis Fungoides & Sezary Syndrome





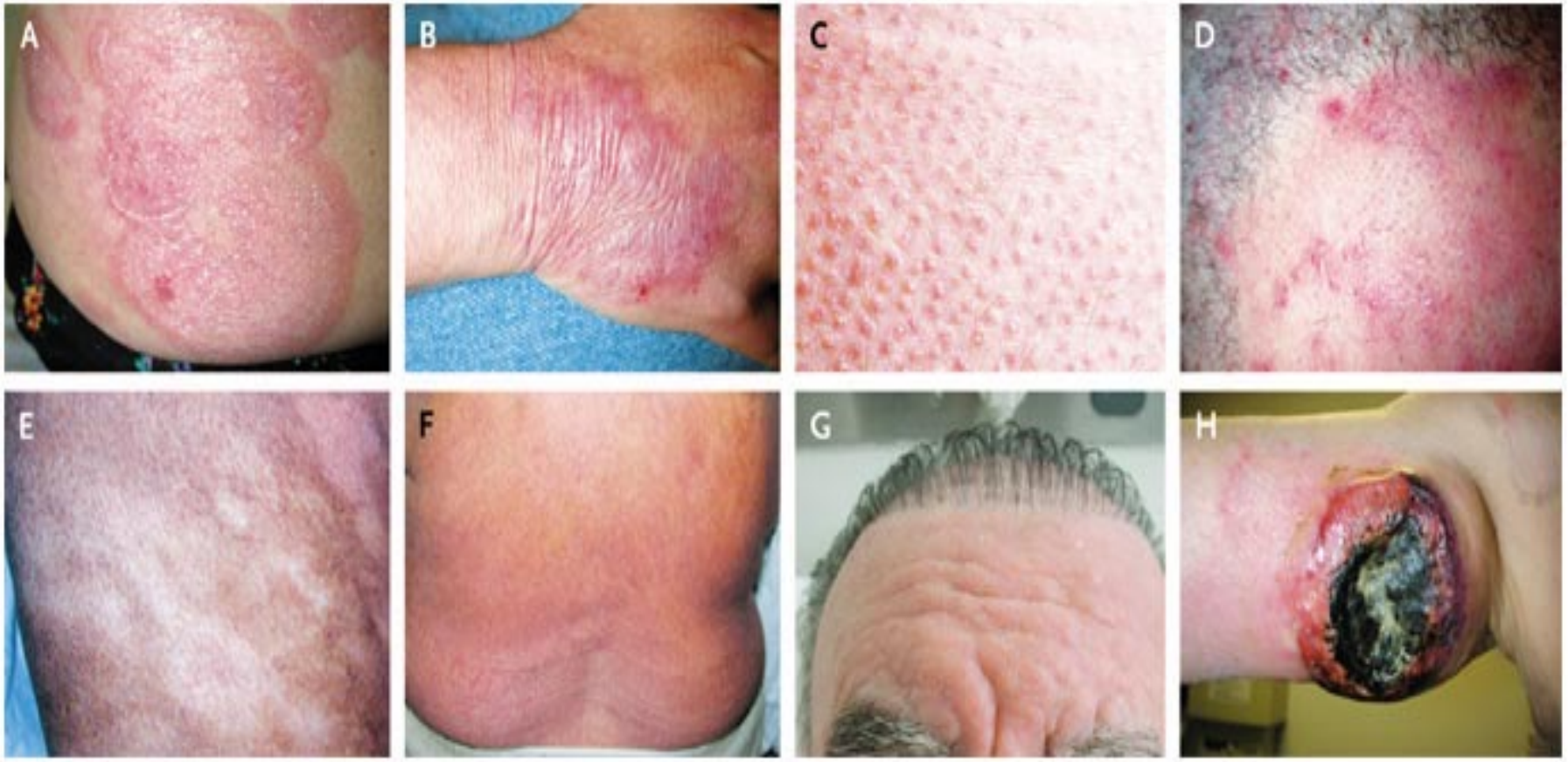


Girardi M et al. NEJM 2004

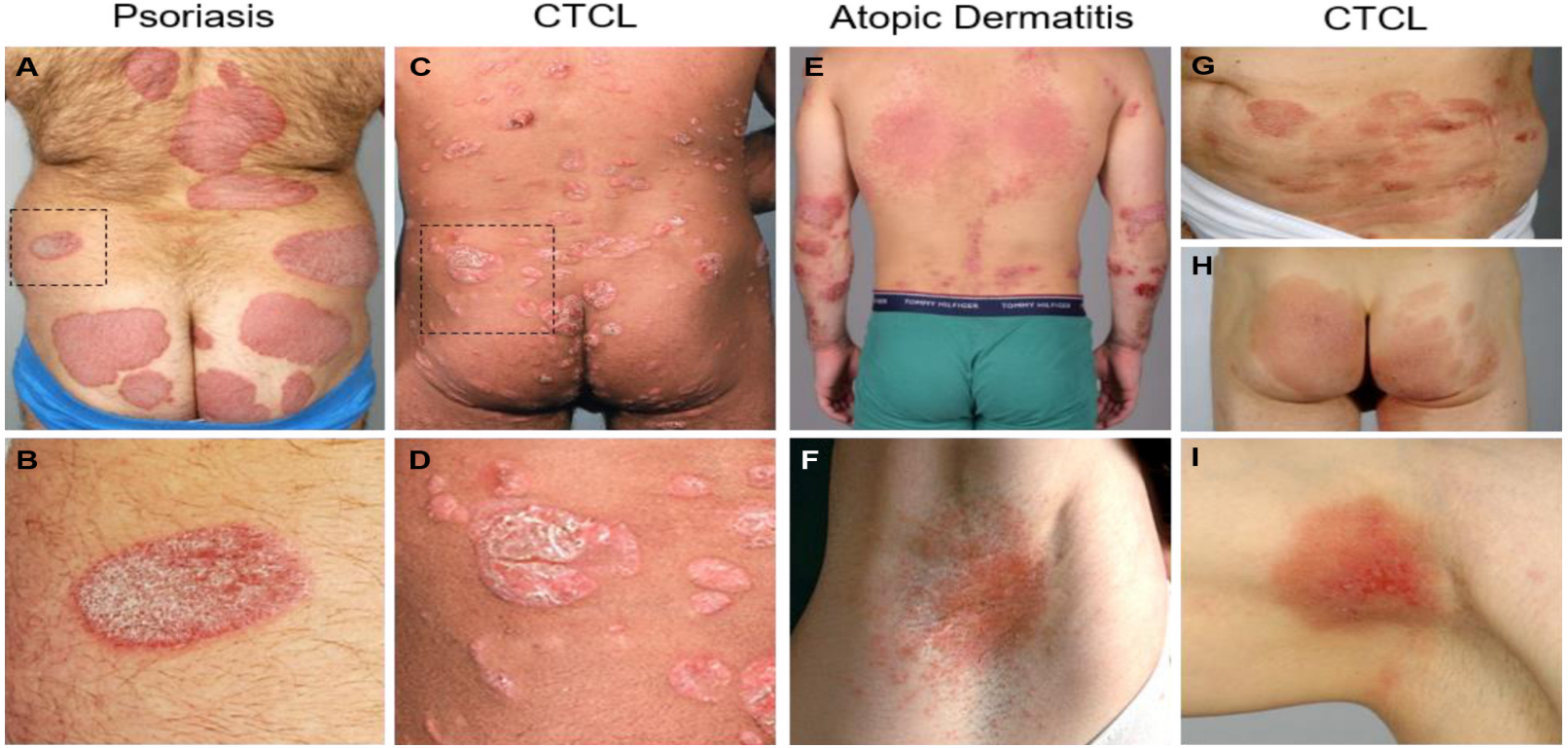
Mycosis Fungoides Variants

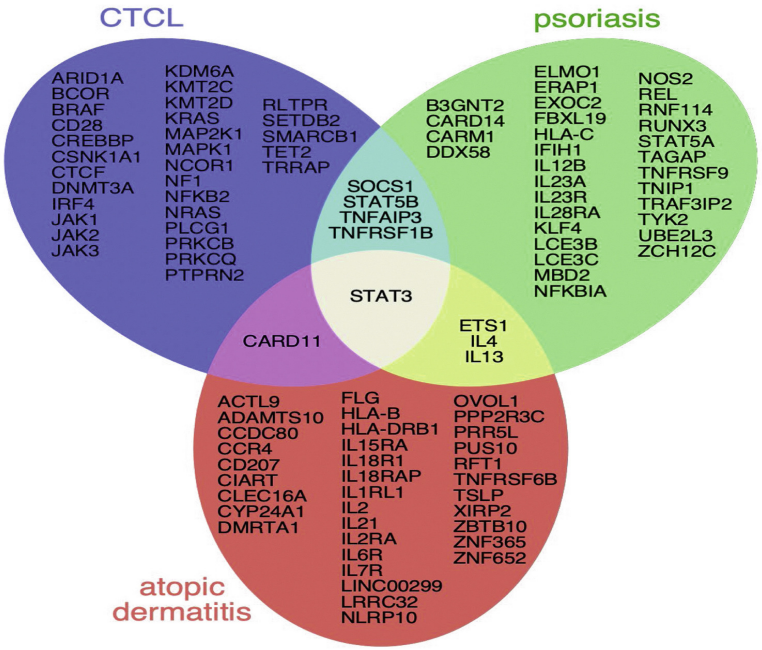
- Clinical variants with conventional histopathological features: 14
- Clinical variants with peculiar histopathological features: 13
- Histopathological variants: 6
- Immunophenotypic variants: 3

Mycosis Fungoides Variants



Girardi M et al. NEJM 2004;350:1978-88





Roediger et al. J Aller Clin Immunol 2022

Differential Diagnosis of Erythroderma

Exfoliative dermatitis (≥80% BSA)

50% with preexisting skin condition

30% idiopathic

<5% malignancy-associated

Most common causes:

- Atopic dermatitis
- Psoriatic erythroderma
- Drug-induced: fever, eosinophilia, lymphadenopathy
- Erythrodermic pityrias rubra pilaris
- Staphyloccocal scaled skin syndrome

Mycosis Fungoides: Diagnostic Criteria: 4 Points Necessary for Dx

Criteria	Scoring System
Clinical	
Basic	
Persistent and/or progressive patches/thin plaques	2 points for basic criteria and 2 additional criteria 1 point for basic criteria and 1 additional criterion
Additional	
(1) Non-sun-exposed location	
(2) Size/shape variation	
(3) Poikiloderma	
Histopathological	
Basic	2 points for basic criteria and 2 additional criteria 1 point for basic criteria and 1 additional criterion
Superficial lymphoid infiltrate	
Additional	
(1) Epidermotropism without spongiosis	
(2) Lymphocytic atypia	
Molecular biology	1 point for clonality
(1) Clonal T-cell receptor rearrangement	
Immunopathological (Immunohistochemical)	
(1) <50% CD2+, CD3+, and/or CD5+ T cells	
(2) <10% CD7+ T cells	
(3) Epidermal/dermal discordance of CD2, CD3, CD5, or CD7 (T-cell antigen deficiency confined to the epidermis)	1 point for one or more criteria

Pimpinelli N et al. J Am Acad Dermatol. 2005.

Principles of Management

Mycosis Fungoides & Sezary Syndrome
Principles of Therapy

- Multidisciplinary approach – stage/compartment based
- Skin directed (MF) vs Systemic therapy (SS)
- ECP monotherapy: FDA approved frontline therapy for SS
- ECP combinations: IFN, Mogamulizumab, Romidepsin
- Supportive therapy: topical steroids, antipruritic tx, bleach baths, prophylactic ATBx

FDA Approved Agents for CTCL and PTCL

Year	Drug	Disease
1999	Denileukin diftitox	MF/SS
2000	Bexarotene	MF/SS
2006	Vorinostat	MF/SS
2009	Romidepsin	MF/SS, PTCL
2009	Pralatrexate	PTCL
2011	Romidepsin	CTCL
2011	Brentuximab vedotin	PTCL
2017	Brentuximab vedotin	MF/SS
2018	Mogamulizumab	MF/SS

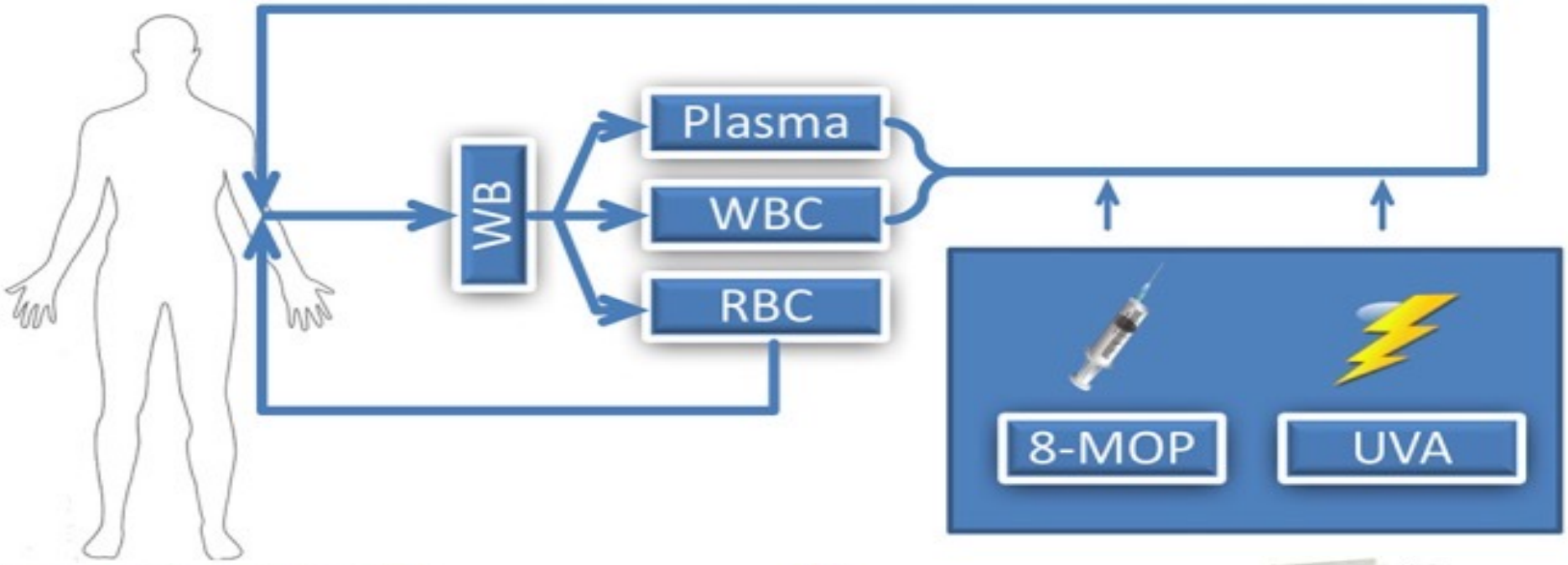
6 drugs FDA approved for CTCL in past 25 years

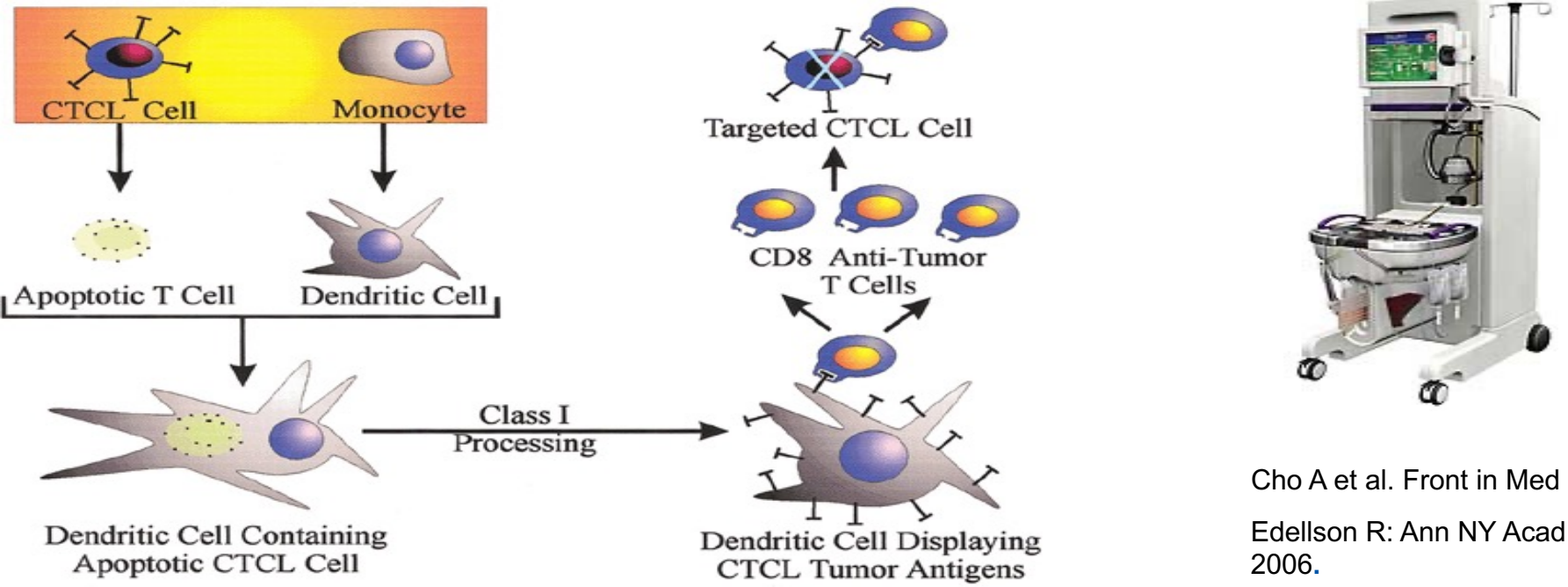
TABLE 5: SÉZARY SYNDROME (Stage IVA1 or IVA2) - MFSS-11[a,b,c,d]

SUGGESTED REGIMENS		TREATMENT CONSIDERATIONS (SEE ALSO GENERAL CONSIDERATIONS ON MFSS-A [1 of 12])
Low-Intermediate Burden (eg, ASC <5 K/mm³)	**High Burden (eg, ASC >5 K/mm³)**	
Preferred Regimens (alphabetical order) • Systemic therapy + skin-directed therapy (limited/local or generalized including phototherapy as indicated for stage of disease) Bexarotene ECP Interferon alfa[b] Methotrexate Mogamulizumab Romidepsin Vorinostat • Combination therapy ECP + interferon alfa[b] or retinoid ECP + interferon alfa[b] + retinoids Retinoid + interferon alfa[b] Other Recommended Regimens (alphabetical order) • Systemic therapy + skin-directed therapy Alemtuzumab Brentuximab vedotin Gemcitabine Liposomal doxorubicin Pembrolizumab Pralatrexate Useful in Certain Circumstances (alphabetical order) • Systemic therapy + skin-directed therapy (limited/local or generalized including phototherapy as indicated for stage of disease) Acitretin Interferon gamma-1b Isotretinoin	Preferred Regimens (alphabetical order) • Systemic therapy + skin-directed therapy (limited/ local or generalized including phototherapy as indicated for stage of disease) Mogamulizumab Romidepsin • Combination therapy ECP + interferon alfa[b] or retinoid ECP + interferon alfa[b] + retinoids Retinoid + interferon alfa[b] Other Recommended Regimens (alphabetical order) • Systemic therapy + skin-directed therapy Alemtuzumab Bexarotene Brentuximab vedotin ECP Gemcitabine Interferon alfa[b] Liposomal doxorubicin Methotrexate Pembrolizumab Pralatrexate Vorinostat Useful in Certain Circumstances (alphabetical order) • Systemic therapy + skin-directed therapy (limited/ local or generalized including phototherapy as indicated for stage of disease) Acitretin Interferon gamma-1b Isotretinoin	1. In the randomized ALCANZA trial (Miles Prince H, et al. Lancet 2017;390:555-566), brentuximab vedotin was more effective than methotrexate or bexarotene in patients with previously treated MF (≥ stage IB). Patients with SS were excluded from the ALCANZA trial. 2. In the randomized MAVORIC trial (Kim YH, et al. Lancet Oncol 2018;19:1192-1204), mogamulizumab was more effective than vorinostat in patients with previously treated MF (≥ stage IB) and SS. Responses were higher in patients with blood involvement (stage III or stage IV disease) than those with stage IIB or stage IB/IIA disease. Patients with MF-LCT were excluded from the MAVORIC trial. 3. Alternative retinoids (acitretin or isotretinoin) could be considered in place of bexarotene. 4. There is limited safety data for the use of TSEBT in combination with systemic retinoids, HDAC inhibitors (such as vorinostat or romidepsin), or mogamulizumab, or combining phototherapy with vorinostat or romidepsin. 5. Patients with disease achieving a clinical benefit and/or those with disease responding to treatment should be considered for maintenance or tapering of regimens to optimize response duration.

Note: All recommendations are category 2A unless otherwise indicated.
Clinical Trials: NCCN believes that the best management of any patient with cancer is in a clinical trial. Participation in clinical trials is especially encouraged.

Extracorporeal Photopheresis





Cho A et al. Front in Med 2018

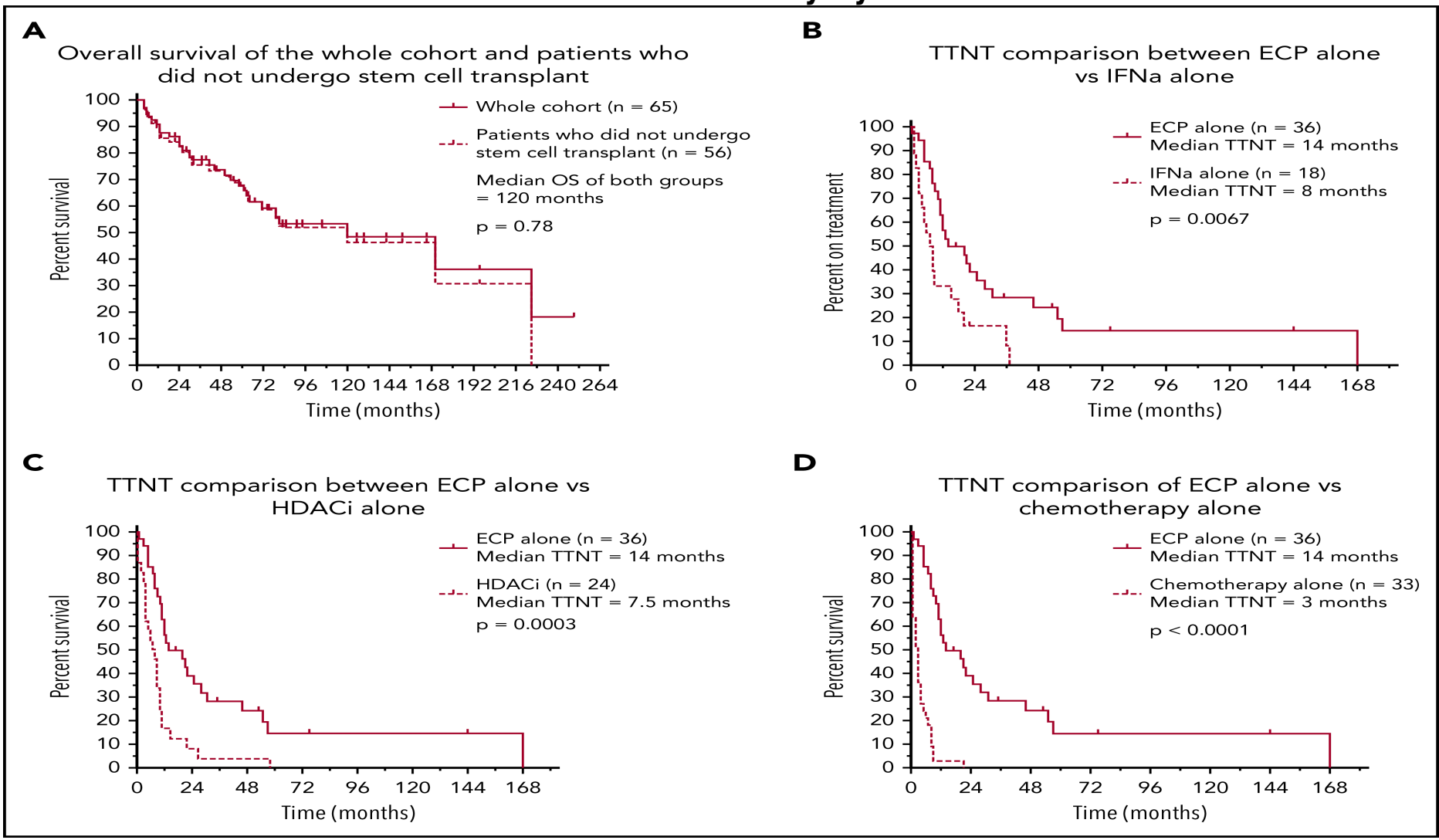
Edellson R: Ann NY Acad Sci, 2006.

Extracorporeal Photopheresis in Erythrodermic CTCL

Study	N	ORR (%)	CR (%)	PR (%)
Edelson et al. 1987	37	73	24	35
Zic et al. 1992	20	55	25	30
Koch et al. 1994	34	53	15	38
Duvic et al. 1996	34	50	18	32
Vonderheid et al. 1998	36	33	14	19
Bisaccia et al. 2000	37	54	14	40

Alfred A et al. BJHaem 2017

Prolonged Survival with the Early Use of a Novel Extracorporeal Photopheresis Regimen in Patients with Sézary Syndrome



The median follow-up: 48 months (range 1-225 months),

Median predicted OS of 120 months.

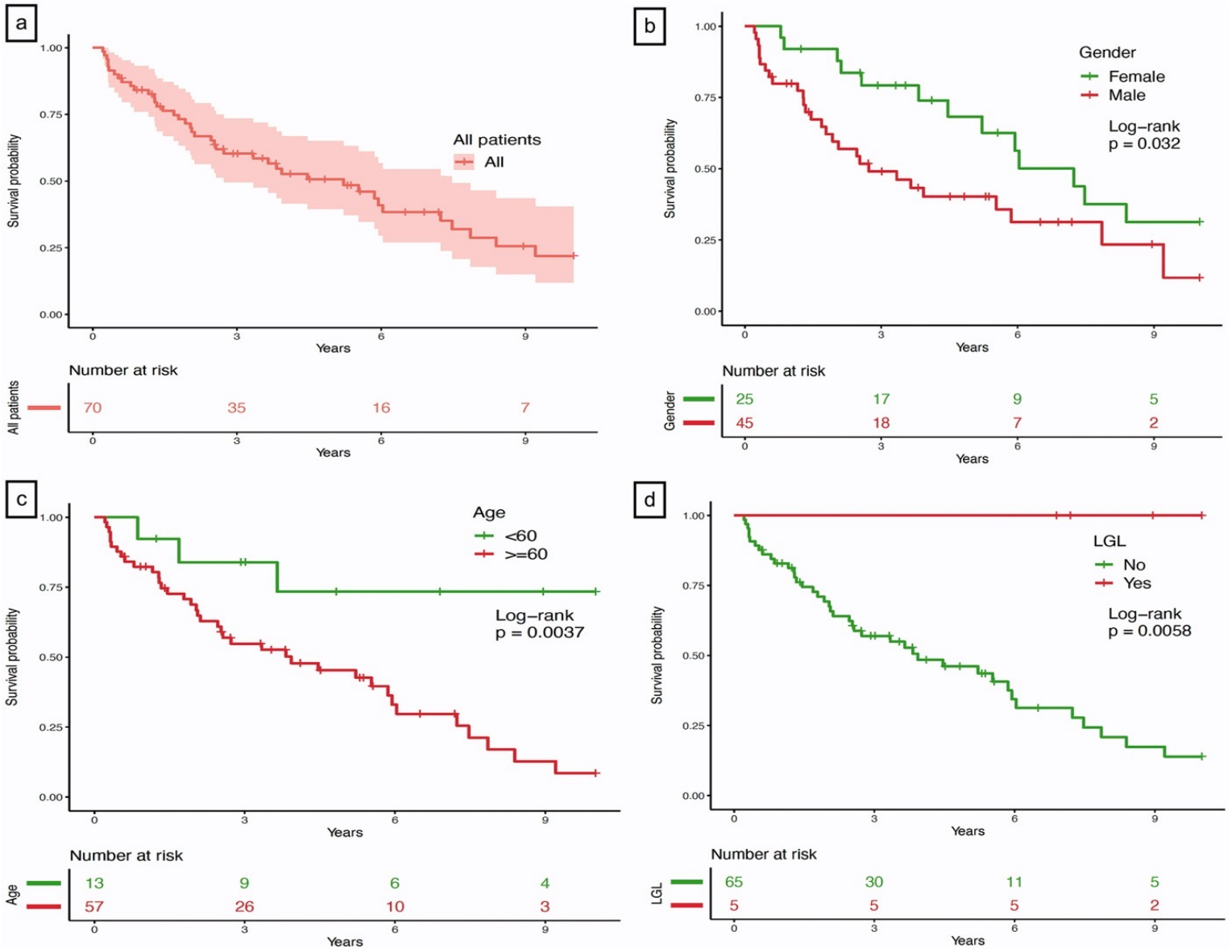
ECP in 88% of pts the 1st to 3rd lines either as a monotherapy or in combination with other agents

Median TTNT superior when compared with interferon, HDACI, immunotherapy or chemotherapy

TTNT of 47 months.

Crystal Gao et al. Blood, 2019.

Clinical Characteristics and Prognostic Factors of 70 patients with Sezary Syndrome Moffitt Cancer Center Experience



1-year OS 84%, 5-year OS 50%

Zhang Y et al. Leuk Lymphoma 2022

Clinical Trials with Sezary Syndrome Patients

Study	Agent	N, SS/Total	ORR (%)
Booken et al.	ECP+IFNa+PUVA	12/24	42
Richardson et al.	IFNa+IFNg+Retinoid+sagramostin	28/28	89
Jumbo et al.	IFNa	11/51	25
Duvic et al.	Bexarotene	17/94	24
Duvic et al.	Gemcitabine	11/33	73
Lunding et al.	Alemtuzumab	7/22	86
Querfeld et al.	Alemtuzumab	17/19	84
Quereux et al.	Liposomal Dox	10/25	60
Whittaker et al.	Romidepsin	13/96	31
Olsen et al.	Vorinostat	30/74	33
Kim et al.	Mogamulizumab	30/81	37
Khodadoust et al.	Pembrolizumab	15/24	38

Adapted from Alpdogan O et al. Chin Clin Oncol 2019

Efficacy and Safety of E7777 (improved purity Denileukin diftitox [ONTAK]) in Patients with Relapsed or Refractory Cutaneous T-Cell Lymphoma: Results from Pivotal Study 302 (NCT01871727)
Foss FM et al. Blood (ASH) 2022 abstr.

Multicenter, open label, single-arm registration study	IRC Primary Efficacy Analysis E7777 9ug/kg (N=69)	Investigator Assessment E7777 9 ug/kg (N=71) (+2 pts with visceral disease)
ORR (CR+PR) n%	25 (36.2)	30 (42.3)
95%CI	(25.0, 48.7)	30.6, 54.6)
Complete response (CR)	6 (8.7)	6 (8.5)
Partial Response (PR)	19 (27.5)	24 (33.8)
Stable disease	36 (52.2)	33 (46.5)
Clinical benefit (CR+PR+SD), n%	34(49.3)	38 (43.5)
DOR (months)	6 (52%), 12 (20%)	
95% CI	(37.0, 61.6)	(41.3, 65.5)

Primary efficacy: 69 pts, stages: I-III, median # of prior therapies: 4

Lacutamab in Patients with Advanced Sezary Syndrome: Results from an Interim Analysis of the Tellomak Phase 2 Tria

Bagot M et al. Blood ASH, 2022 (abstr.)

TELLOMAK, international open-label, phase 2 trial with multiple cohorts (NCT03902184). Cohort 1: relapsed/refractory SS after at least 2 prior systemic therapies including mogamulizumab	N=37
Global ORR (ITT) n%	8 (21.6)
95%CI	(11.4, 37.2))
Blood response (ORR)	14 (37.8)
Blood (CR)	8 (21.6)
Lymph node response	1 (3.5)

Lacutamab 750 mg, IV weekly × 5 wks, then every 2 w × 10, then every 4 w until progression or unacceptable toxicity.
SS patients: only B2 eligible

CAR -T Cell Therapy in CTCL/PTCL

CAR	Disease	Study	Sites
ALTCAR.CD30 ALTCAR.CD30.CCR4	CD30+ HL and NHL	**NCT0360157**	**UNC**
CD5.CAR	T-cell NHL	**NCT03081910**	**Baylor Univ**
CD4.CAR	R/R T-cell NHL/leukemia	**NCT03829540**	**Stony Brook Univ**
CD7.CAR	NK/T-cell NHL, T-LBL	**NCT04004637**	**China**
AUTO4	TCRBC1+ T-NHL	**NCT03590574**	**UK**
CTX-130	CD70 PTCL/CTCL	**NCT04502446**	**USA**
MT-101	CD5+ PTCL/CTCL	NCT05138458	**USA**

www.clinicaltrials.gov

Advances in Detection of Malignant MF/SS Populations

CTCL: Staging and Response Assessment in Blood Using Multiparameter Flow Cytometry

B0 0-249/uL
B1 ≥ 250 – 999/uL
B2 ≥1 000/uL

Overlap with non-malignant CD4+CD7- and CD4+CD26- populations

ISCL/EORTC

CD4+CD7- and CD4+CD26-

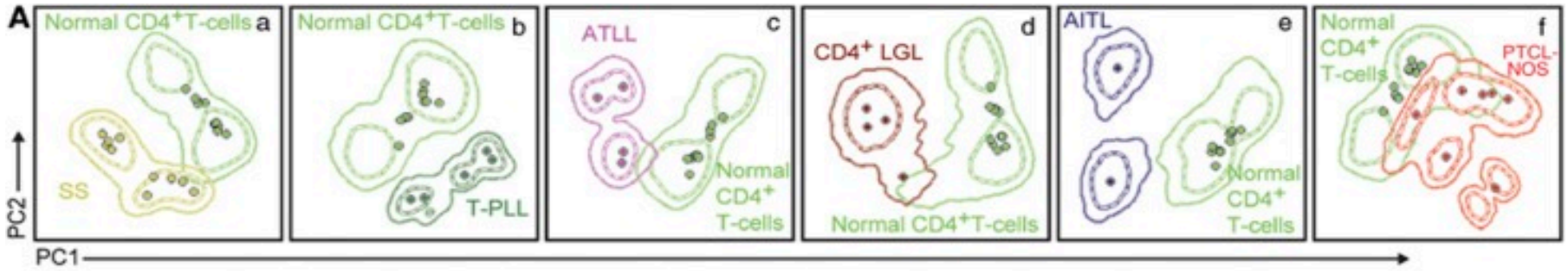
Criteria for Diagnosis of Sezary Syndrome

Clinical Trial Purposes

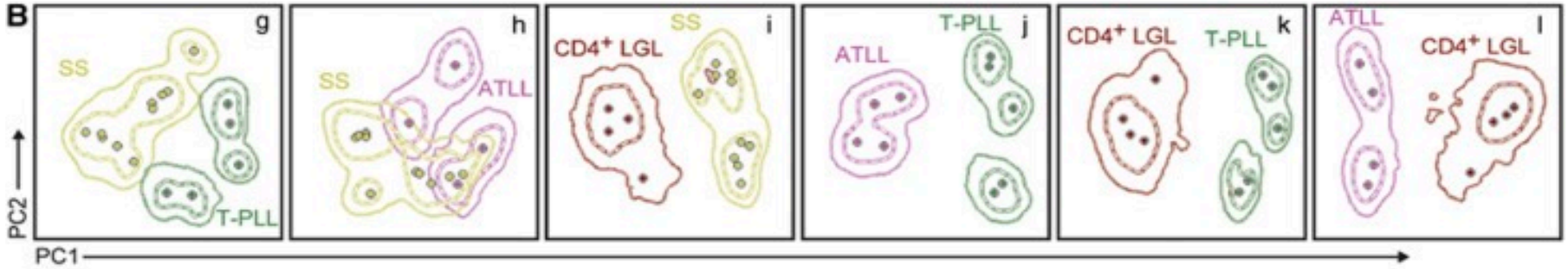
Olsen EA et al. Blood 2022

- Erythrodermic MF/SS
- B2 blood involvement
- Clone in blood that matches skin

EuroFlow antibody panels for standardized *n*-dimensional flow cytometric immunophenotyping of normal, reactive and malignant leukocytes



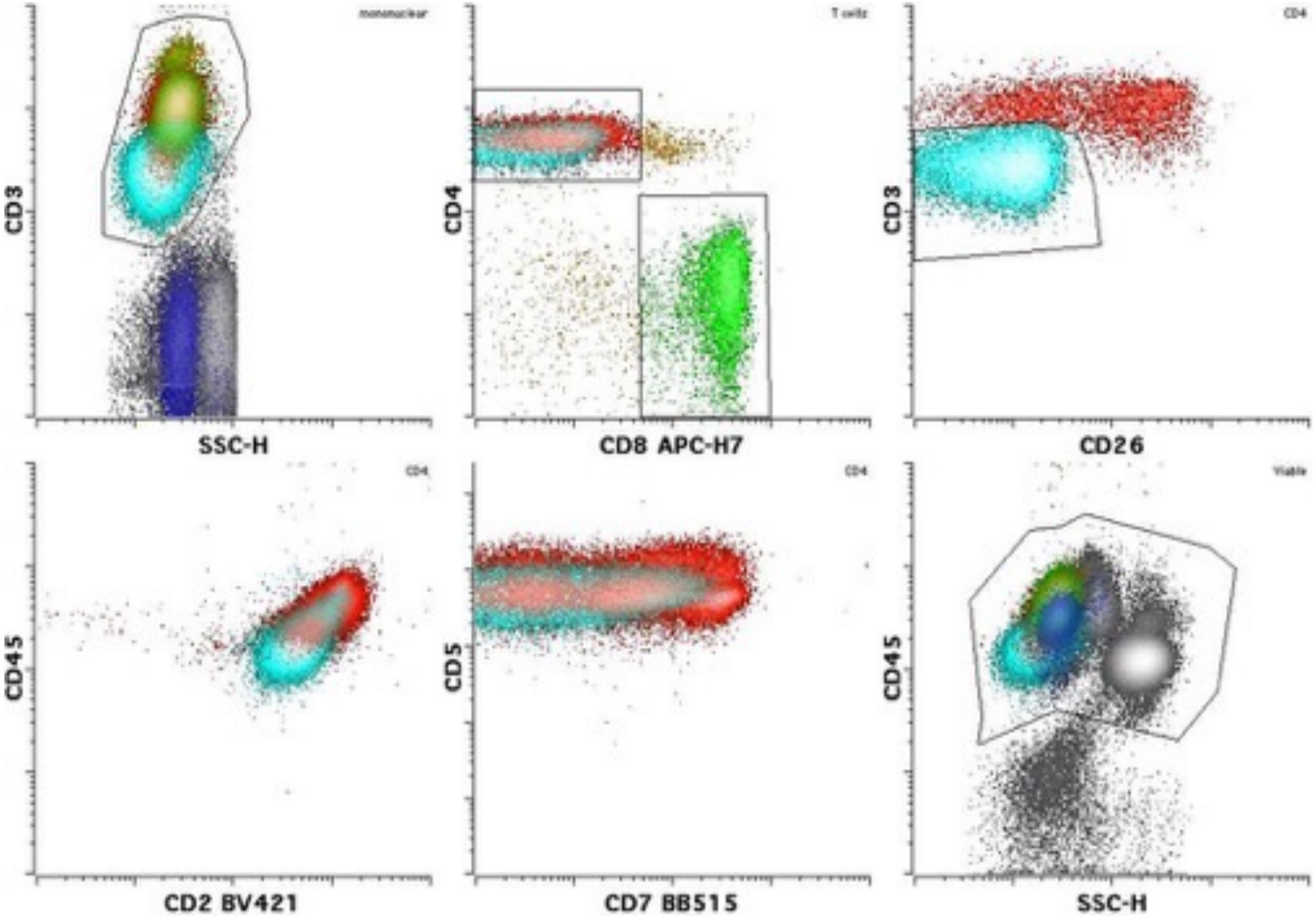
CD2	15%	CD45RA	14%	CD45RA	11%	CD28	15%	HLADR	13%	CD45RA	10%
CD45RO	15%	CD45RO	13%	CD7	11%	CD57	10%	CD279	11%	CyGranzyme B	8%
CD45RA	9%	CD3	10%	CD2	10%	CD27	9%	CD45RA	10%	CD7	8%
CD26	8%	CD26	10%	CD45RO	9%	CyGranzyme B	9%	CD3	10%	CD27	8%
CD7	8%	CD8	8%	HLADR	8%	CD45RA	8%	CD7	8%	CD3	7%
CD279	7%	CD27	5%	CD25	7%	CD7	8%	CyGranzyme B	7%	CD28	6%



CD2	13%	CD45RO	22%	CD28	15%	CD7	12%	CD28	14%	CD28	14%
CD26	12%	HLADR	15%	CD45RA	11%	CD26	11%	CD26	10%	CD45RA	13%
CD7	11%	CD45RA	14%	CD57	11%	HLADR	9%	CD197(CCR7)	9%	CD57	10%
CD45RO	10%	CD2	12%	CD2	9%	CD197(CCR7)	8%	CD7	8%	CD45RO	9%
CD8	8%	CD25	9%	CD27	9%	CD2	8%	CD45RA	8%	CD2	8%
CD197(CCR7)	7%	CD5	5%	CD197(CCR7)	7%	CyTcl1	8%	CD57	7%	CD27	7%

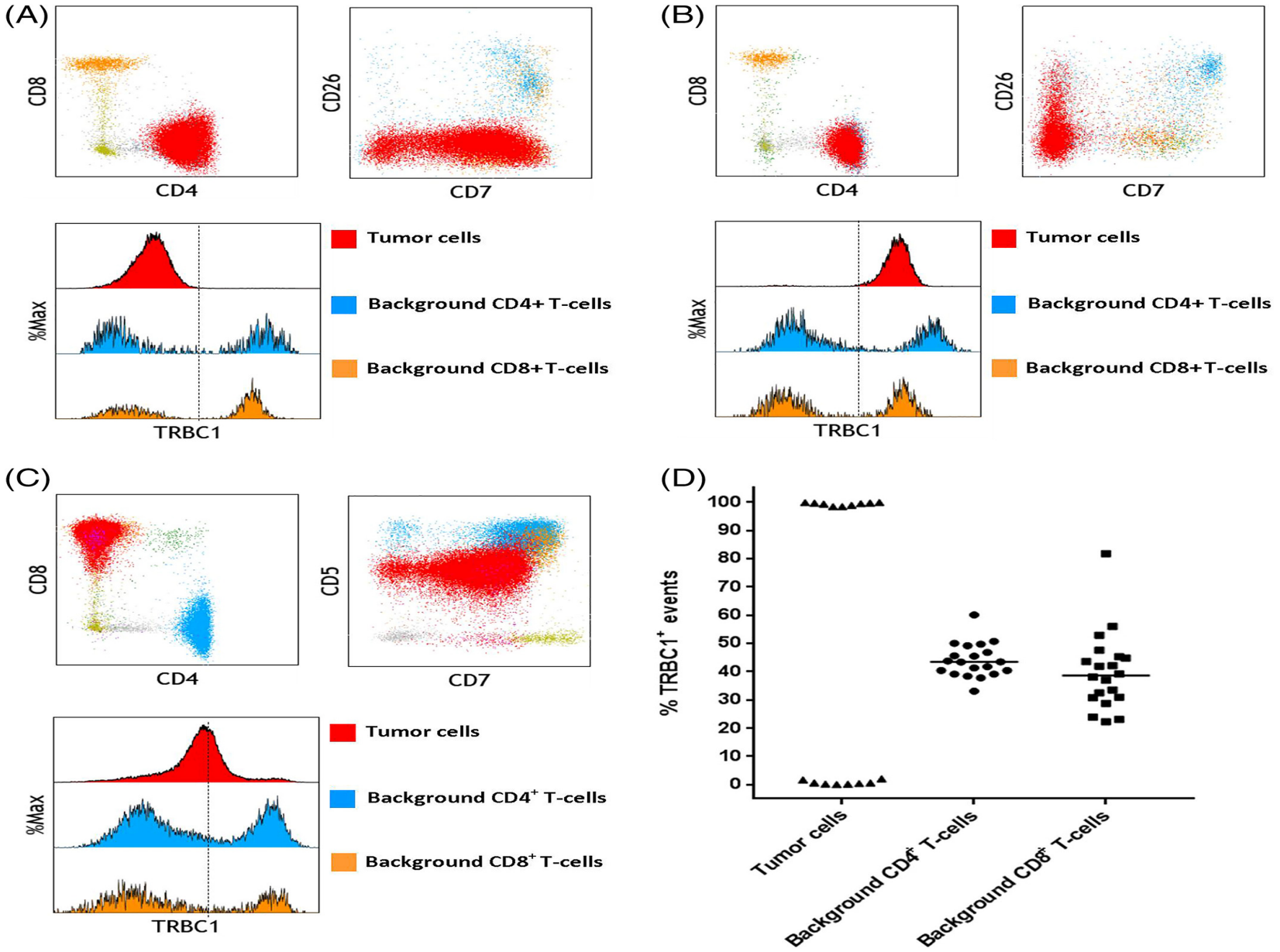
Van Dongen JJM et al. Leukemia 2012

Use of Multicolor-Flow Cytometry in Sezary Syndrome



Pulitzer MP et al. Cytometry b Clin Cytom 2022

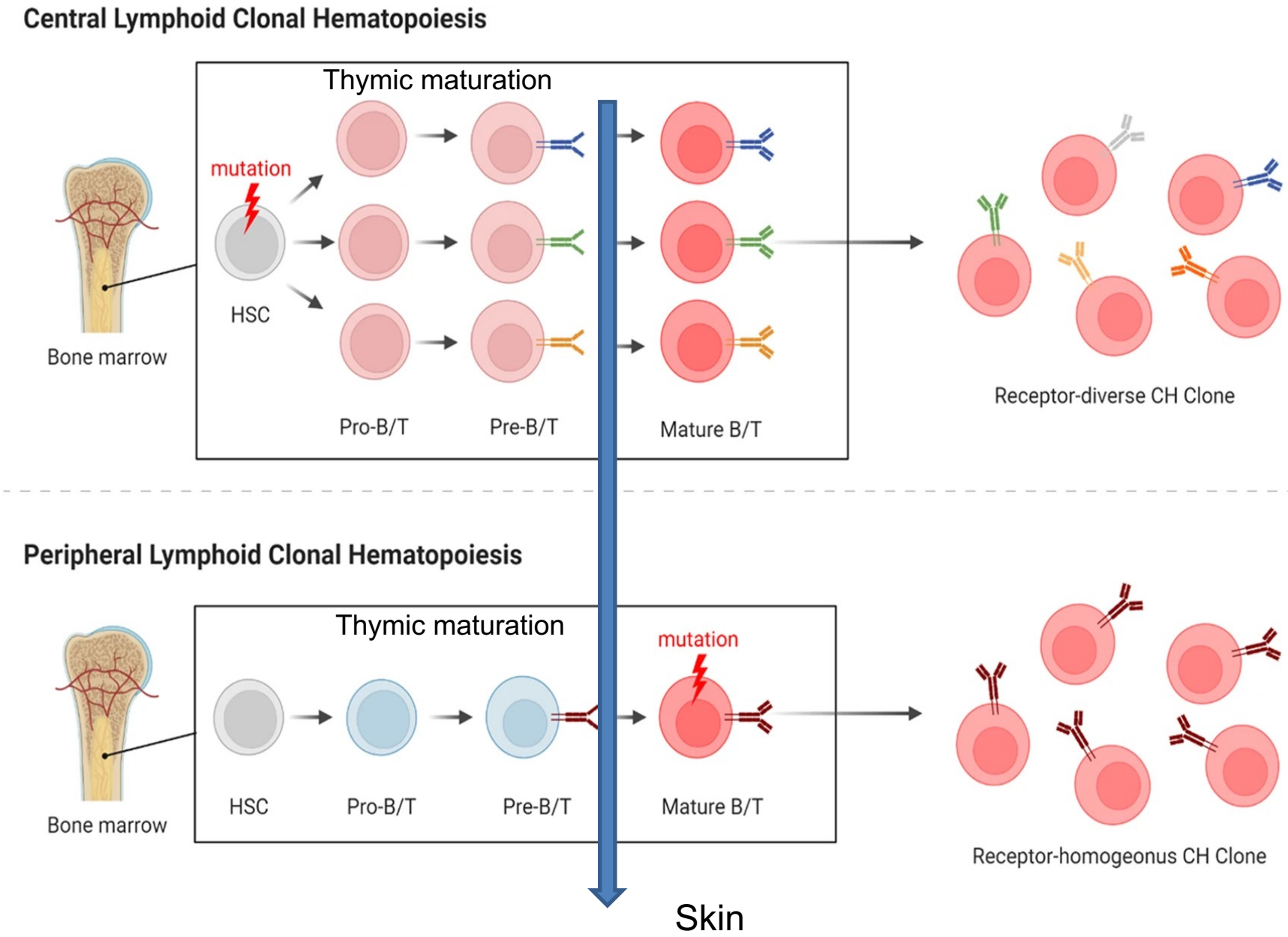
TRBC1 Single Antibody Detection of T-Cell Receptor αβ Clonality by Flow Cytometry



Cytometry Part B Clinical, 2019,

Cell of Origin

Can CTCL Arise on the Background of L-CHIP?



Adapted from Von Beck K et al. Blood Cancer Journal 2023

Naïve/memory/effector T-cell Phenotypes in Leukemic Cutaneous T-cell Lymphoma: Putative Cell of Origin Overlaps Disease Classification

Mycosis Fungoides

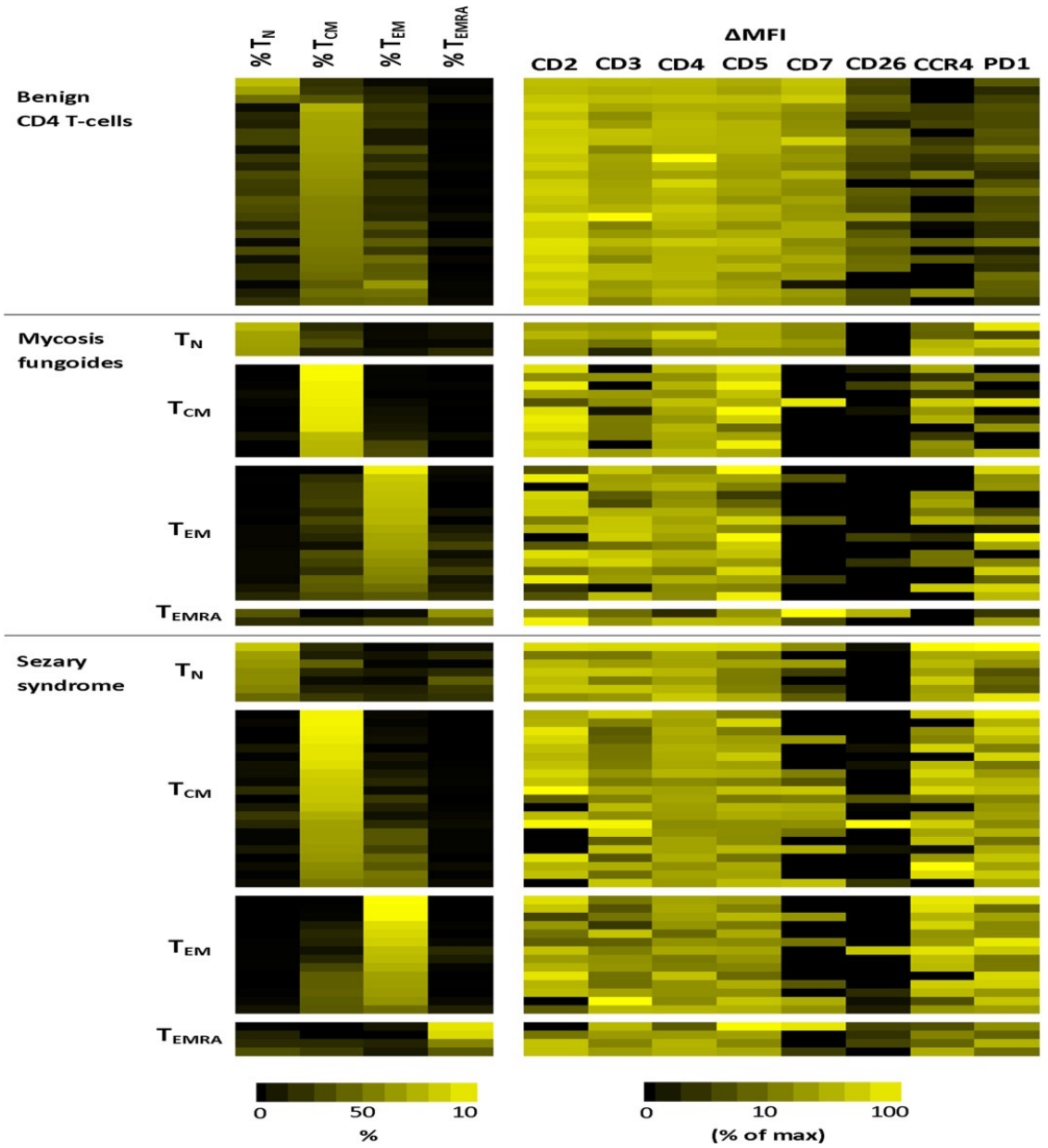
CCR7(-), CD62L(-), CD27(-)
Effector memory phenotype (T^{EM})

PD-1 (low/-)

Sezary Syndrome

CCR7(+), CD62L(+), CD27(+)
Central memory phenotype (T^{CM})

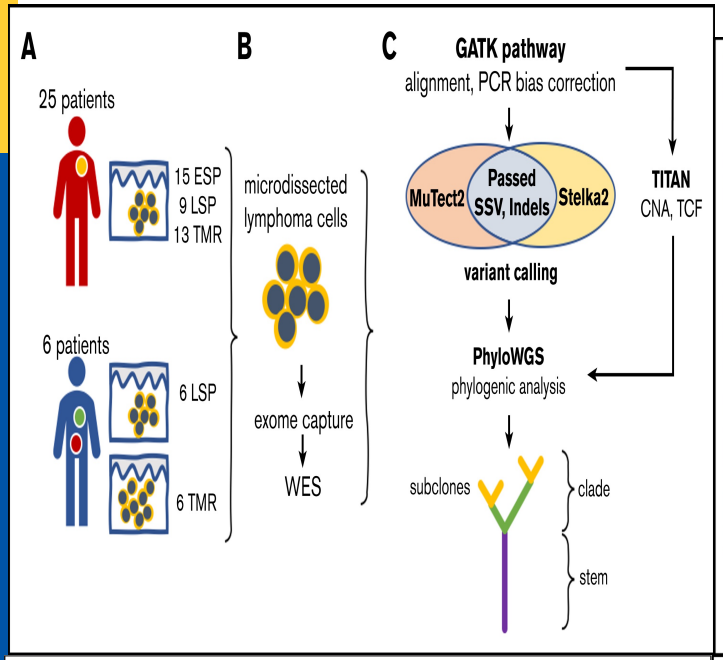
PD-1 (high)

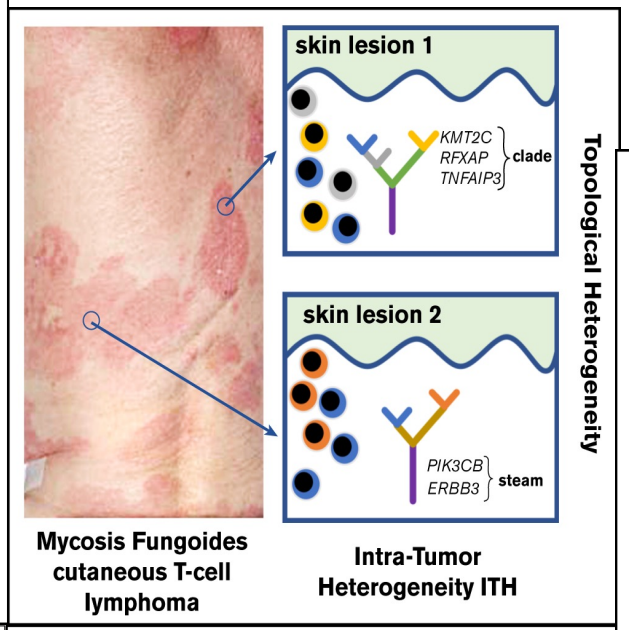


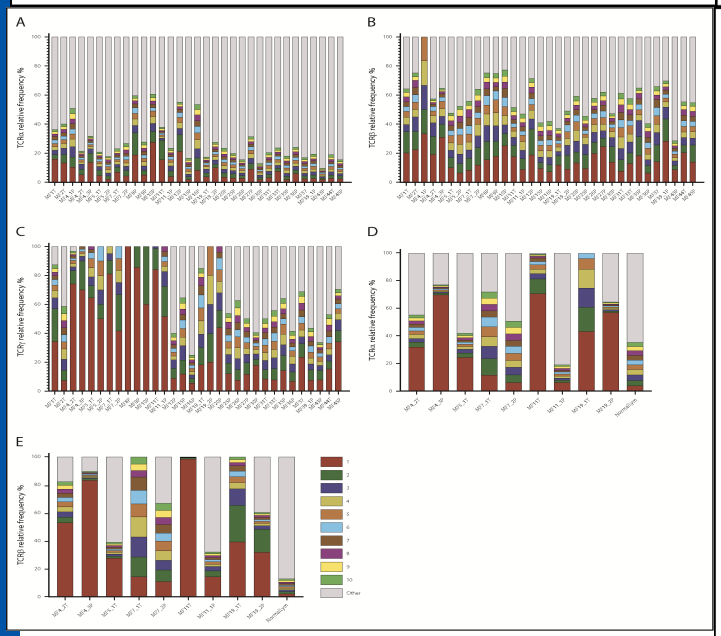
Campbell JJ, et al. Blood 2010;116:767
Clark RA, et al. Sci Transl Med;4:117
Cetinozman F, et al. Arch Dermatol;148:1379

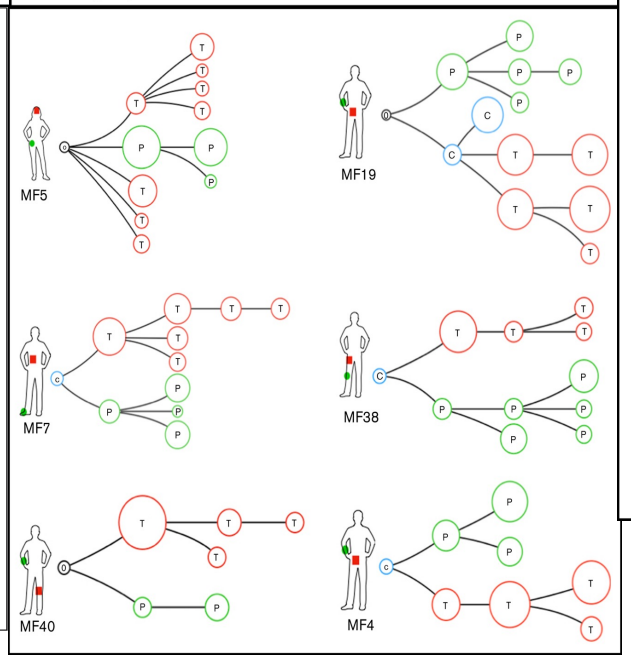
Horna P et al. Cytometry Part B: Clinical Cytometry, 2018

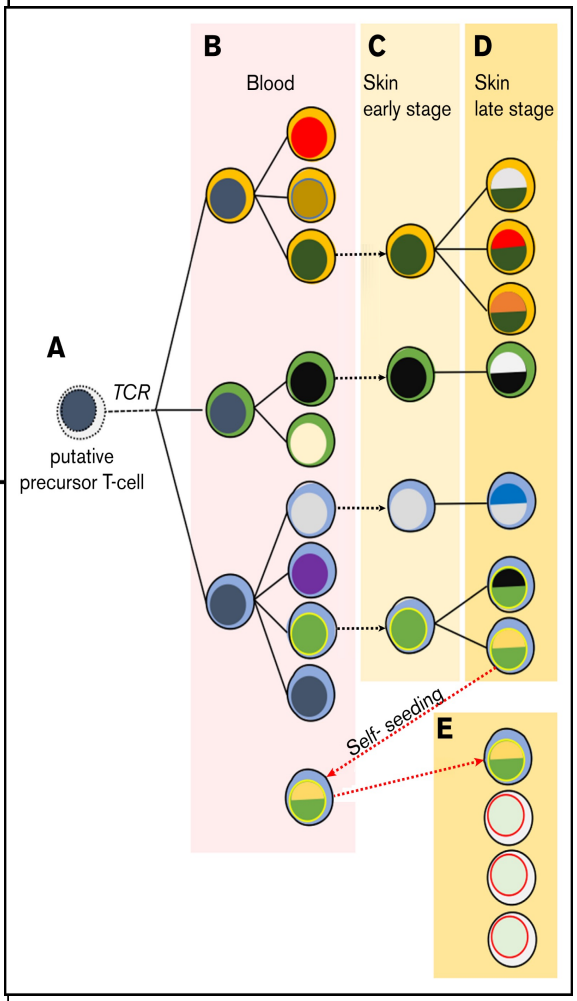
Branched Evolution and Genomic Intratumor Heterogeneity in the Pathogenesis of Cutaneous T-Cell Lymphoma











Iyer A et al. Blood Adv 2019

Iyer A et al. Blood Adv 2020

Mycosis Fungoides is Clonotypically Heterogeneous Disease

Multiple circulating T cell clones in peripheral blood : median 11 (range 2-80) in 29 MF patients (stage I-IV) argues against origin of malignant cells in peripheral tissues

Cutaneous lesion of MF are formed by seeding of clonotypically heterogeneous neoplastic T cell clones from blood

Clonotypes in blood and a skin resemble more than clonotypes between two skin lesions

Circulating MF cells continuously replenish skin lesions of MF

Sezary Syndrome
Mutational Landscape

WES: 551 non-synonymous variants distributed across 525 genes

478 missense mutations and 73 nonsense, splicing, or frameshift mutations

Only 25 recurrent mutations (7 pts)

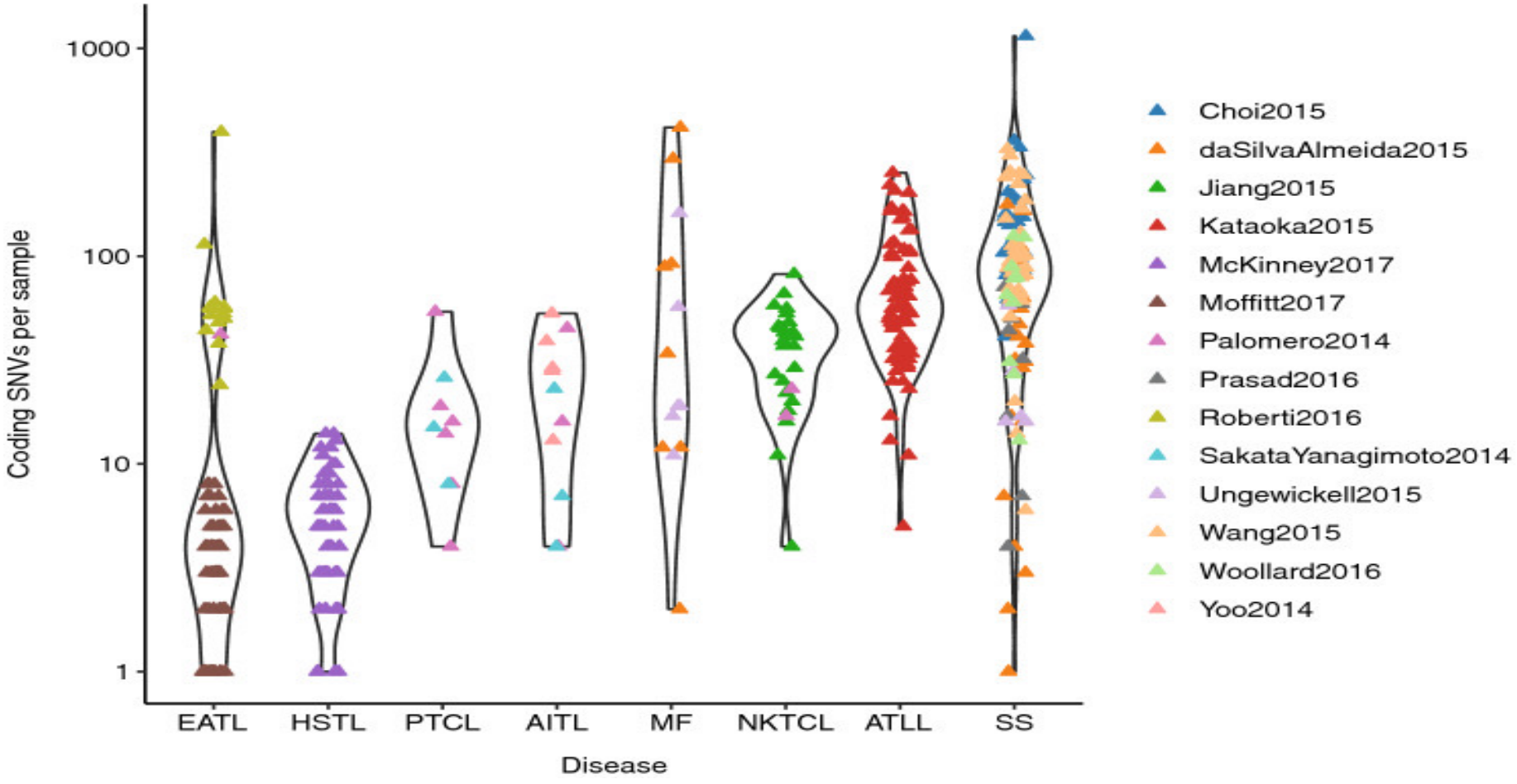
Previously unreported mutations: ANK3, CAMSAP1, C7orf42, CSMD1, DH11, FAT1, FLAD1, FLNB, FRAS1, GLUD2, GRIA2, ITGB8, KCND2, LRP1B, LRP2, MYH4, NRCAM, OR2L2, PAPPA2, PCLO, PKHD1L1, UNC13C, VWA3B, XIRP2, LRP2

Most commonly affected pathways: JAK/STAT/ PPAR, PI3K, FGFR

JAK/STAT, PPAR, PI3K, FGFR

Mirza A-S et al. Front Oncol 2020

Number of Coding SNVs per Sample



Jones CL et al. Scientific Reports 2021

Single Cell RNA –seq and VDJ-seq in SS

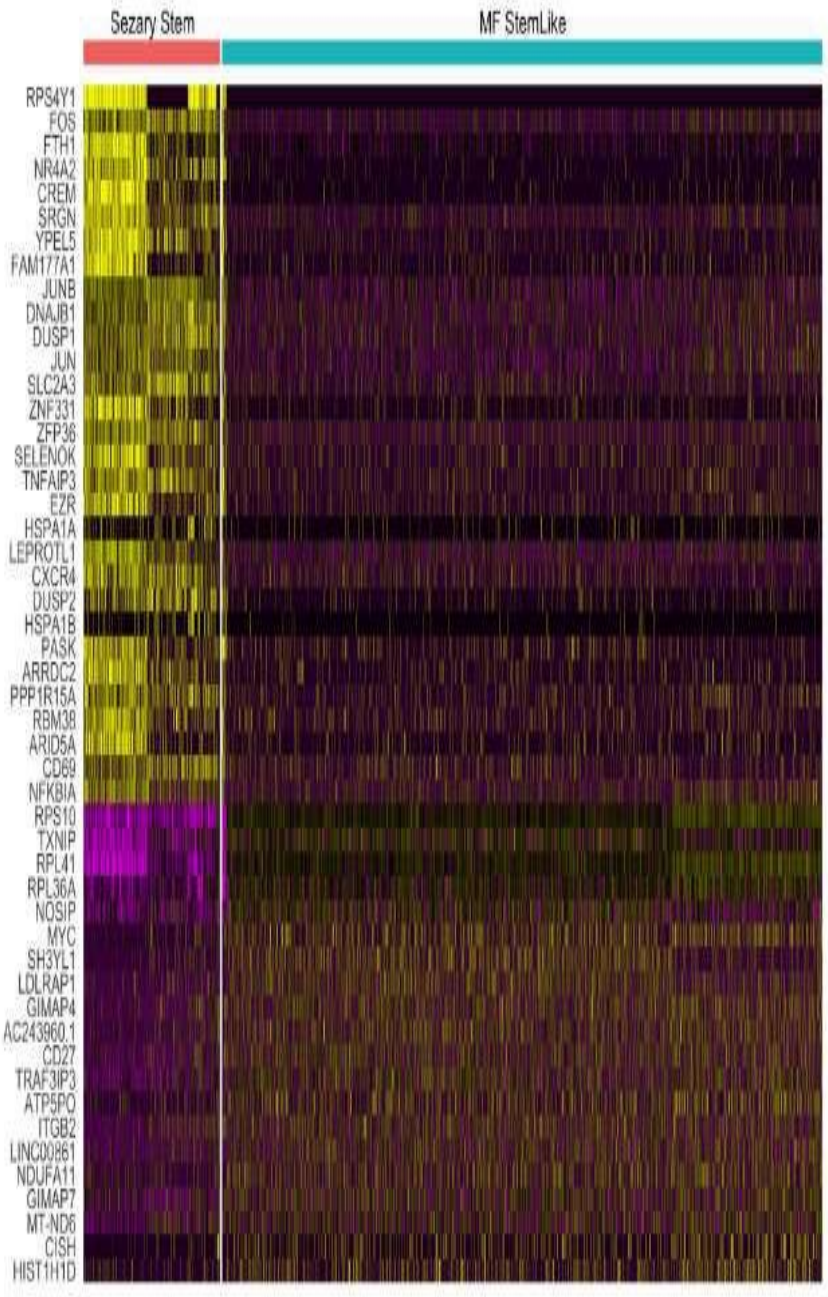
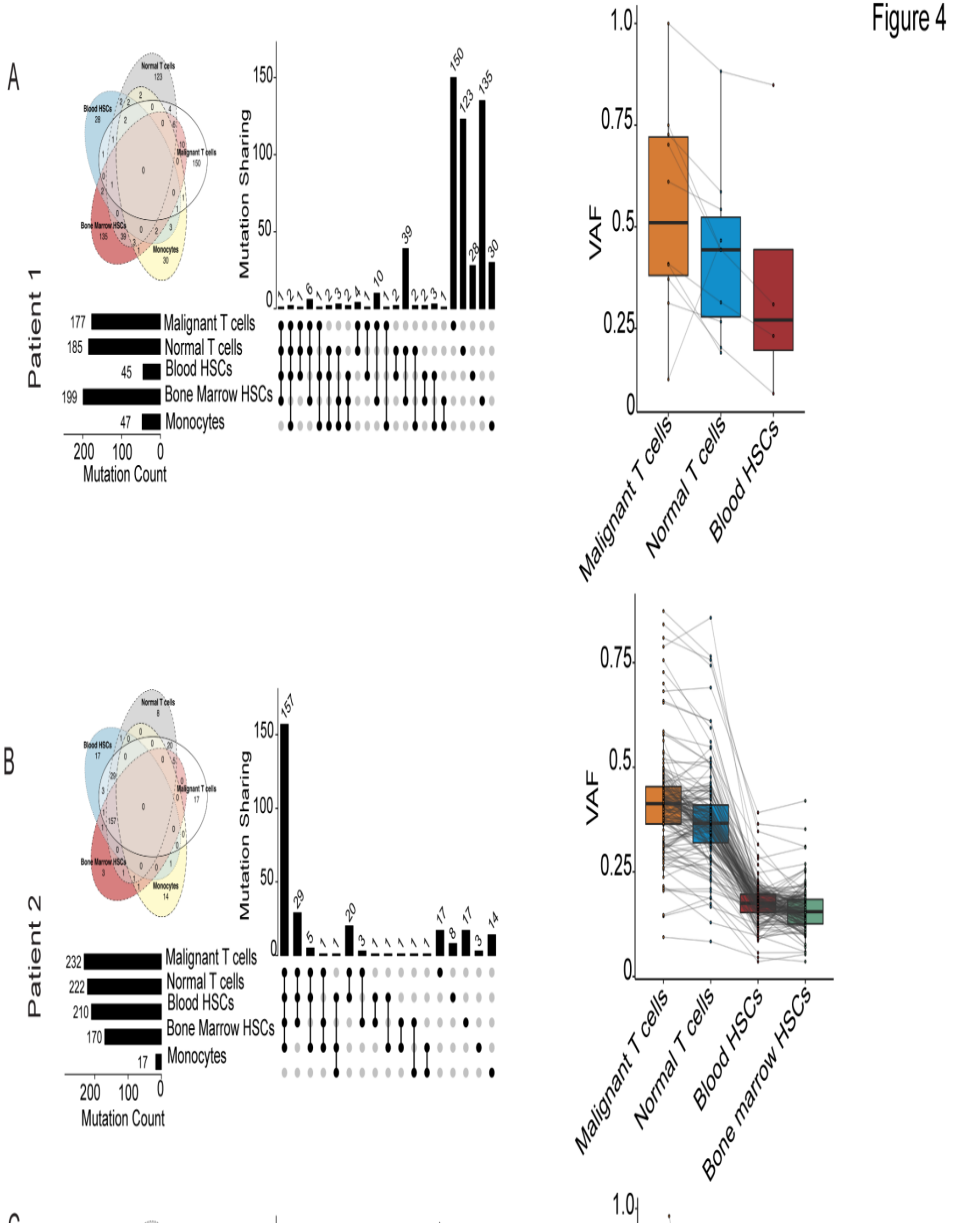


Figure 4



Harro C. et al. unpublished

MCC Study: Search for Cell of Origin in MF/SS

Hematopoietic CD34+ stem cells (HSC) >200 non-synonymous mutations in all patients with SS

HSC carry numerous mutations shared with malignant Sezary cells and normal T cells (ARID1A, ARID1B, TP53, UNC80, SCN2A, TNK2, GLI2, PKD2, MPA6)

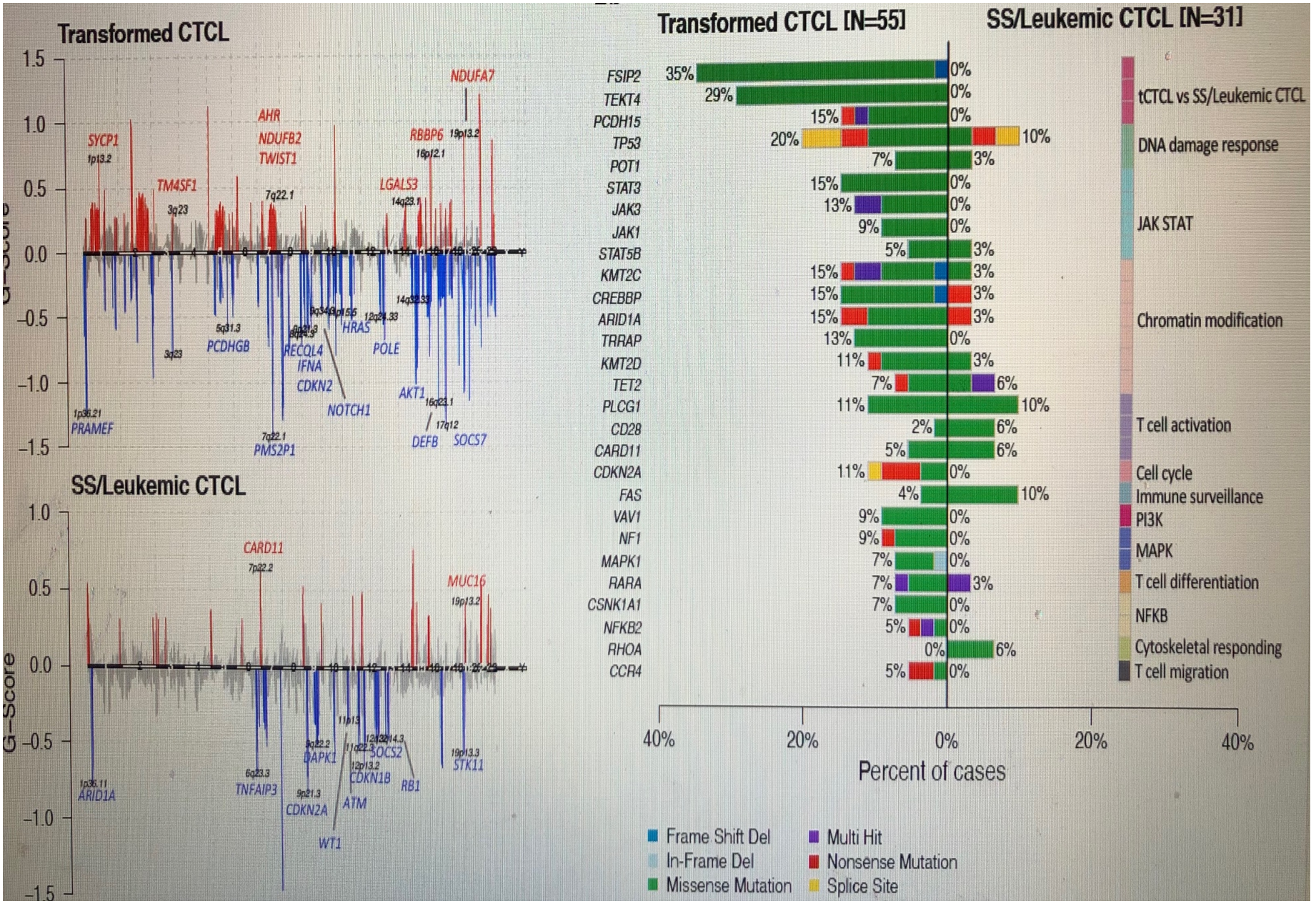
MF and SS malignant cells have diverse range of clonotypes

Sezary cells express sjTREC sequences and appeared to be recent thymic emigrants

Mutated hematopoietic progenitors with malignant potential acquire different TCRs in thymus with a potential to expand in the periphery

Harro C et al. unpublished

Transformed MF Exhibits Distinct Genomic Gains and Losses in Contrast to SS



Song X et al. Cancer Discovery 2022

Conclusions

Mycosis Fungoides and Sezary Syndrome are clonotypically and genotypically heterogeneous malignancies

Intra and inter-tumoral genetic diversity of malignant clonotypes could explain low response rate to current therapy

Characterization of L-CHIP in MF/SS and early intervention in high-risk subjects could delay or eliminate clinical manifestation of this disease

Future therapeutic approaches may need to target not only dominant but also high-risk small clones or mutated progenitor cells in BM before they enter thymus

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Comprehensive Care for Patients with CTCL

Photopheresis
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Phototherapy
Dr. Frank L. Glass
Dr. George Cohen

Radiotherapy
Dr. Michael Montejo

Immunotherapy
Dr. Jose Conejo-Garcia
Dr. Javier Pinilla
Dr. Lubomir Sokol

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