Advances in Malignant lymphomas:
The case of extranodal and T-cell lymphomas

Santiago de Chile
April 5-6, 2016

Auditorio Dr. Lucas Sierra
Hospital del Salvador
Av. Providencia 364

Presidents:
Maria Elena Cabrera
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The International T-Cell Projects: from retrospective analysis to prospective data collection

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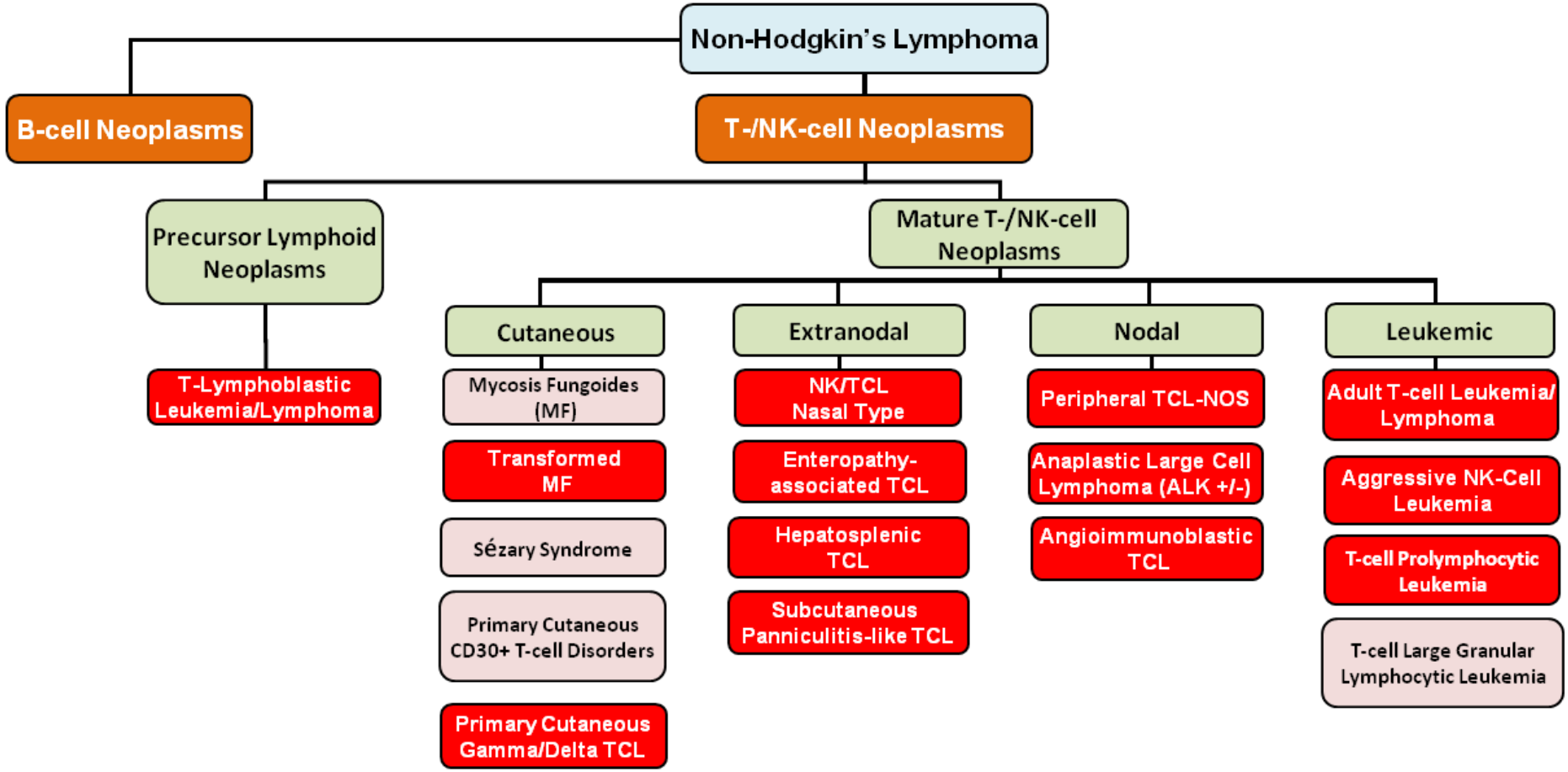
Peripheral T-cell lymphomas (PTCLs)

- clinically and biologically heterogeneous group of mature T-cell and NK-cell neoplasms arising via oncogenic transformation of post-thymic T- and NK cells in peripheral lymphoid organs
- classification relies on
  - ✓ Morphology
  - ✓ Immunophenotype
  - ✓ Clinical/anatomical presentation
- limited recurrent genetic or molecular lesions, most lacking disease specificity
- Expert hematopathology review essential

WHO 2008 Classification of PTCLs



Adapted from Swerdlow SH, et al. *WHO Classification of Tumours of Haematopoietic and Lymphoid Tissues*. 2008

Aggressive | Indolent

PTCLs: Epidemiology

- accounts for ~ 10% to 15% of all NHL
- rare in Western populations, prevalence slightly higher in Asia and Central–South America
- unique geographic distribution of different subtypes
- by some estimates, the incidence of PTCLs is growing significantly
  - ✓ may be driven by an aging population
  - ✓ improvements in diagnosis techniques may also be driving the apparent growth in incidence

International T-cell Project

Vose et al. 2008

International T-Cell Lymphoma Project

- 1,314 cases with PTCL or NK/T cell lymphoma (161 excluded; 1,153 analyzed)
- Newly diagnosed 1990-2002
- 22 sites globally
- Expert Hematopathology review
- Correlation with clinical outcomes

JOURNAL OF CLINICAL ONCOLOGY | ORIGINAL REPORT

International Peripheral T-Cell and Natural Killer/T-Cell Lymphoma Study: Pathology Findings and Clinical Outcomes

International T-Cell Lymphoma Project

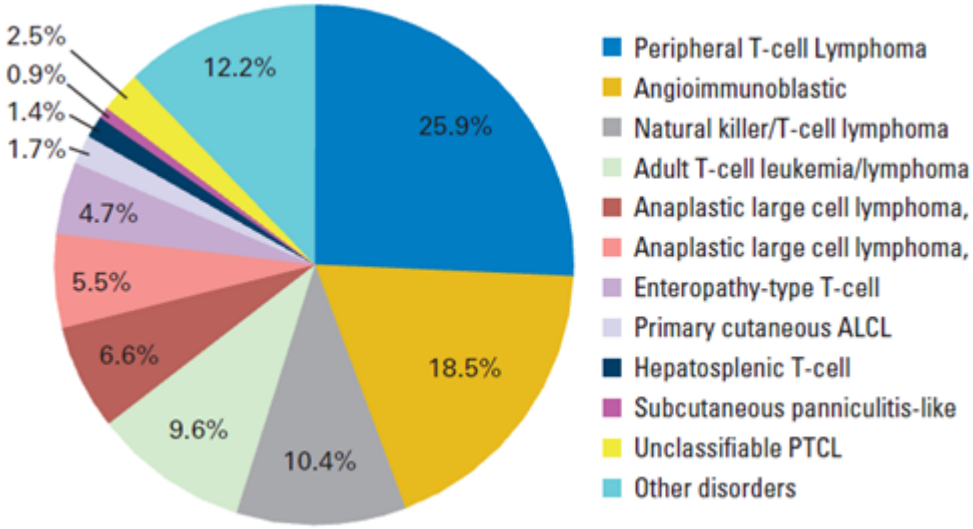


Fig 1. Distribution of 1,314 cases by consensus diagnosis.

Subtypes distribution among regions

Table 1. Major Lymphoma Subtypes by Geographic Region

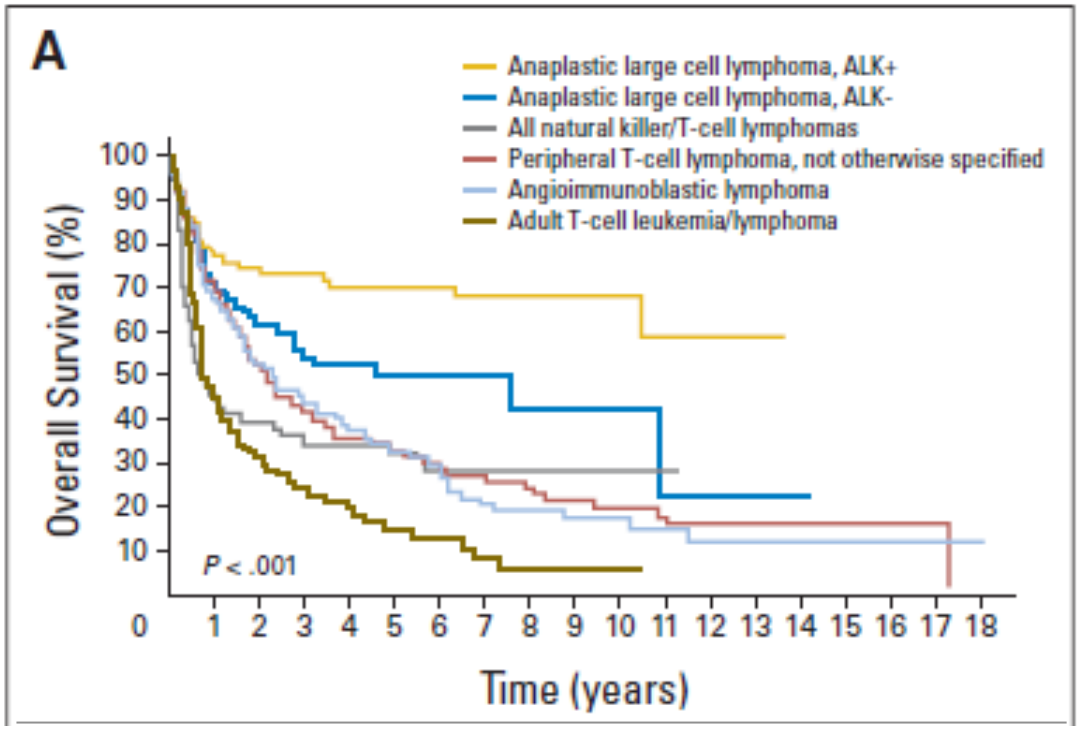
Subtype	% North America	% Europe	% Asia
PTCL-NOS	34.4	34.3	22.4
Angioimmunoblastic	16.0	28.7	17.9
ALCL, ALK positive	16.0	6.4	3.2
ALCL, ALK negative	7.8	9.4	2.6
NKTCL	5.1	4.3	22.4
ATLL	2.0	1.0	25.0
Enteropathy-type	5.8	9.1	1.9
Hepatosplenic	3.0	2.3	0.2
Primary cutaneous ALCL	5.4	0.8	0.7
Subcutaneous panniculitis-like	1.3	0.5	1.3
Unclassifiable T-cell	2.3	3.3	2.4

Abbreviations: PTCL, peripheral T-cell lymphoma; NOS, not otherwise specified; ALCL, anaplastic large-cell lymphoma; NKTCL, natural killer/T-cell lymphoma.

Overall survival

Vose et al.
2008

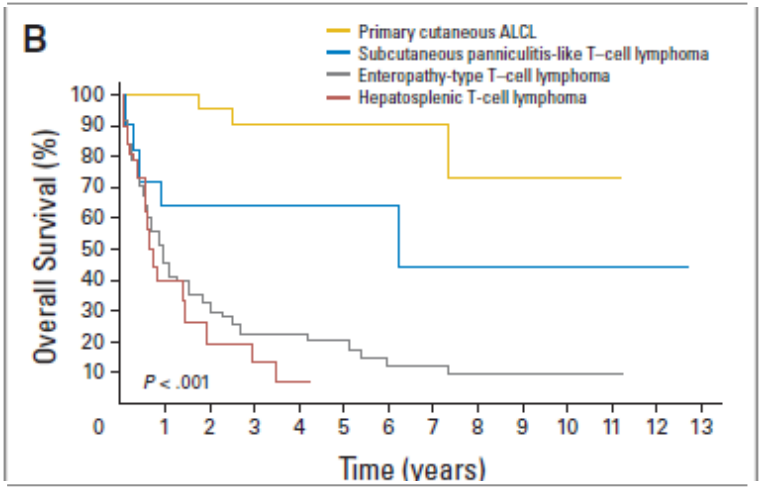
International T-Cell Lymphoma Project



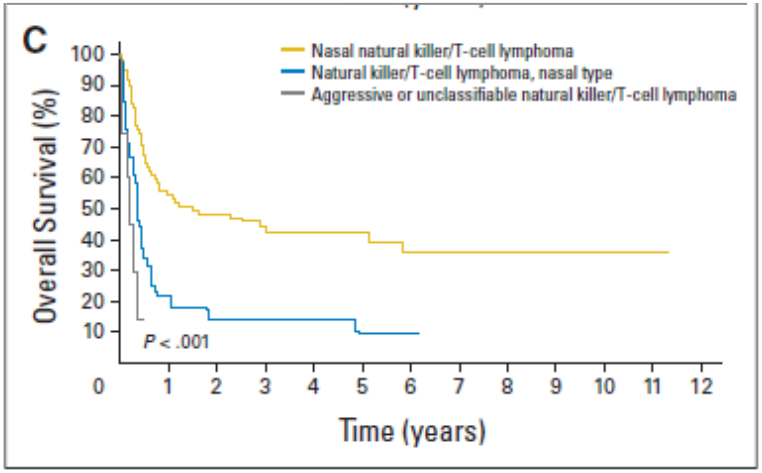
5-yr OS of most frequent subtypes

ALK+ ALCL	ALK– ALCL	PTCL-NOS	AITL	NKTCL	ATLL
70%	49%	32%	32%	32%	14%

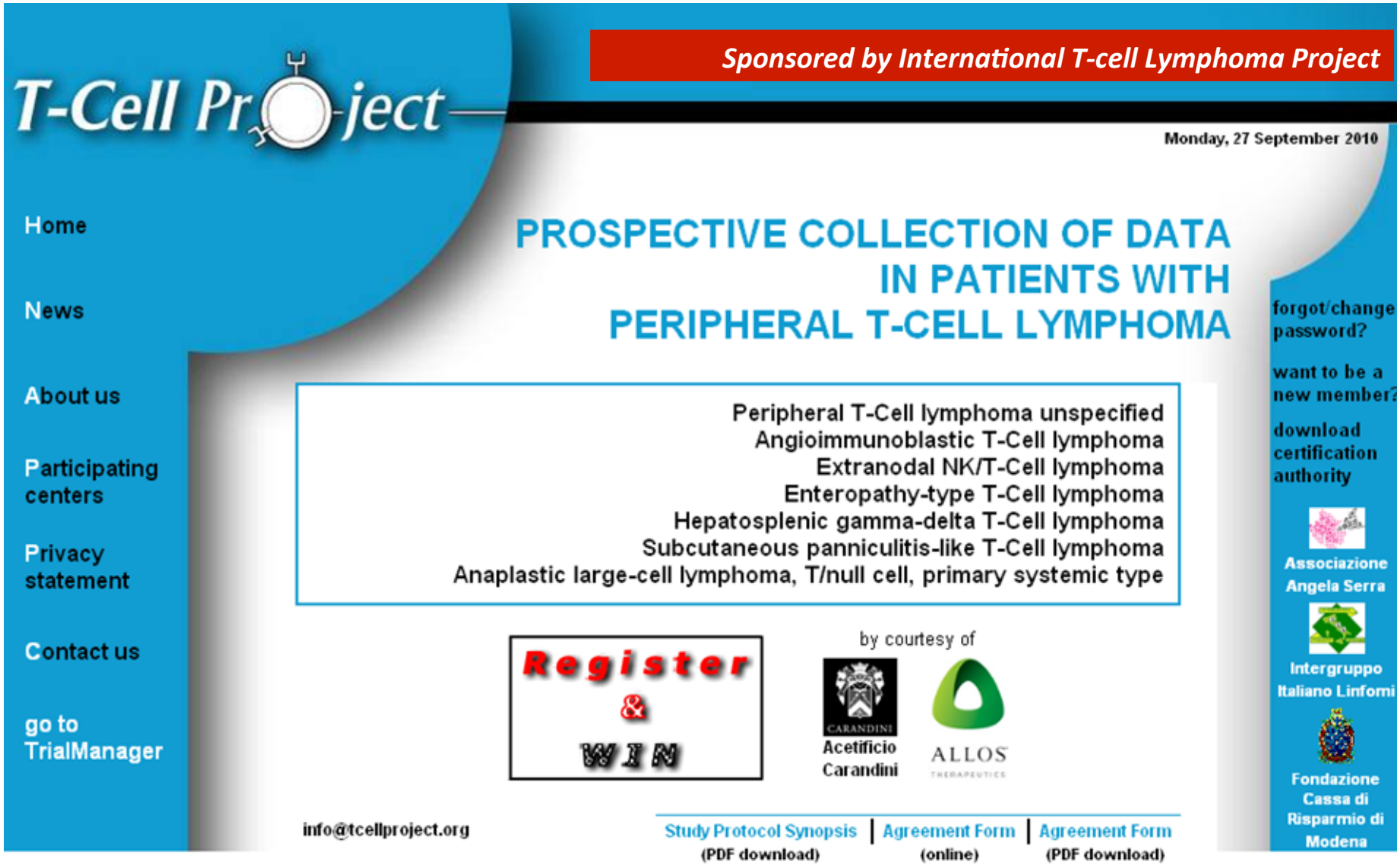
Less frequent subtypes



NKTCL



Study start: September 1, 2006



Study design and Aims

- To verify if a **prospective collection** of data would allow to achieve more accurate information **to better define prognosis** of the most frequent subtypes (PTCL,NOS and AITL) and **to improve knowledge on clinical and biological characteristics** and **outcome** of the more uncommon subtypes
- Sample size calculated on PTCL,NOS and AITL

  (**460 PTCL,NOS + 460 AITL**)
- Primary endpoint: **5-yr OS**

Inclusion Criteria (1)

1. **Previously-untreated patients with *de novo* diagnosis of peripheral T-cell or NK/T-cell lymphoma:**

- ✓ **Peripheral T-cell lymphoma NOS**
- ✓ **Angioimmunoblastic T-cell lymphoma**

- Peripheral T-cell lymphoma, lymphoepitelioid variant
- Peripheral T-cell lymphoma, T-zone variant
- Peripheral T-cell lymphoma, parafollicular variant
- Nasal NK/T-cell lymphoma
- NK/T-cell lymphoma, nasal type
- Anaplastic large-cell lymphoma, T/null cell, ALK+, primary systemic type
- Anaplastic large-cell lymphoma, T/null cell, ALK-, primary systemic type
- Anaplastic large cell lymphoma, small cell variant, ALK+
- Anaplastic large cell lymphoma, lymphohistiocytic variant, ALK+
- Enteropathy- type T-cell lymphoma
- Hepatosplenic T-cell lymphoma
- Peripheral gamma-delta T-cell lymphoma
- Subcutaneous panniculitis-like T-cell lymphoma
- Unclassifiable peripheral T-cell Lymphoma
- Unclassifiable NK-cell lymphoma

Inclusion Criteria (2)

2. **Age over 18**
3. **Clinical data including baseline information on disease localization and laboratory parameters at staging, features of treatment adopted and assurance of follow-up updating for at least 5 years are requested**
4. **Tissue biopsies adequate for diagnosis and classification and available for centralized review**
5. **Diagnosis from September 1, 2006**
6. **Continuous series of patients from each Institution**

Institutions & Patients

as of March 13, 2016	Inst	Pts	%
Recruiting	74	1499	100
Active, Not Yet Recruiting	5	-	-

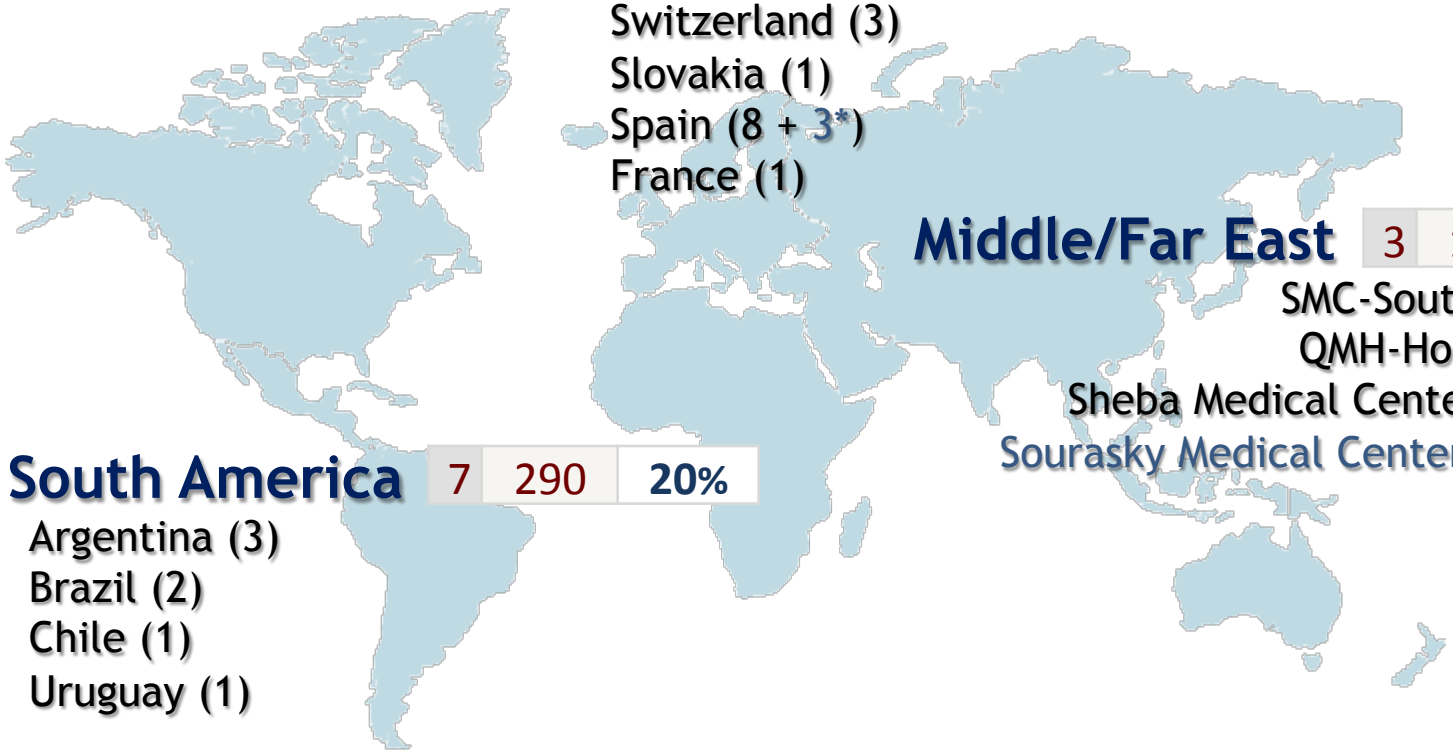
USA 8 | 328 | 22%

MSKCC
MDACC
UNMC
Stanford
CCF
FHCRC
WUStL
Yale

Europe 56 | 649 | 45%

Italy (39 + 1*)
UK (4)
Switzerland (3)
Slovakia (1)
Spain (8 + 3*)
France (1)

* active, not yet recruiting



Middle/Far East 3 | 182 | 13%

SMC-South Korea
QMH-Hong Kong
Sheba Medical Center-Israel
Sourasky Medical Center-Israel*

South America 7 | 290 | 20%

Argentina (3)
Brazil (2)
Chile (1)
Uruguay (1)

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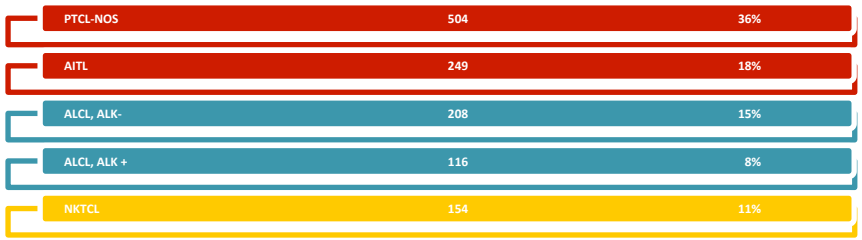
Analysis of data of patients registered up to March 15, 2016 and with available data (N=1,389). Part 1.

Histotype distribution

according to LOCAL/CENTRAL DIAGNOSIS

if review not possible or not yet done local diagnosis is reported

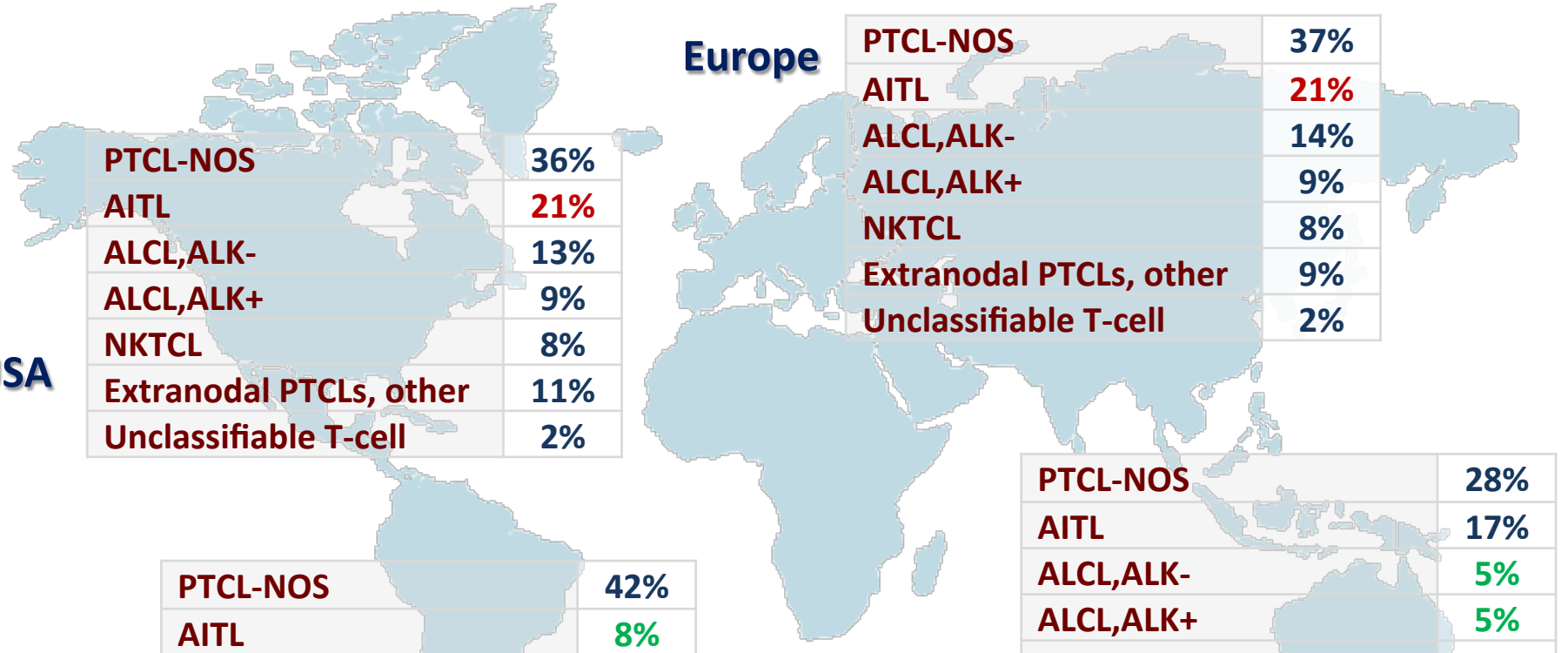


Enteropathy type	62	5%
Hepatosplenic	26	2%
Subcutaneous pann-like	20	1%
Peripheral γδ	13	1%
Unclassifiable T-cell	37	3%

Histologic subtypes distribution (%)

Subtype	Vose et al 2008	International T-Cell Lymphoma Project
	N =1153	N=1389
PTCL-NOS	25.9	36.3
AITL	18.5	17.9
ALCL, ALK +	6.6	8.4
ALCL, ALK -	5.5	15.0
ALCL, primary cutaneous	1.7	-
NK/T-cell lymphoma	10.4	11.1
EATL	4.7	4.5
Hepatosplenic	1.4	1.9
Subcutaneous panniculitis-like	0.9	1.4
Gamma-delta T-cell	< 1	0.9
Unclassifiable T-cell	2.5	2.7

Subtypes by geographic area



USA

PTCL-NOS	36%
AITL	21%
ALCL,ALK-	13%
ALCL,ALK+	9%
NKTCL	8%
Extranodal PTCLs, other	11%
Unclassifiable T-cell	2%

Europe

PTCL-NOS	37%
AITL	21%
ALCL,ALK-	14%
ALCL,ALK+	9%
NKTCL	8%
Extranodal PTCLs, other	9%
Unclassifiable T-cell	2%

South America

PTCL-NOS	42%
AITL	8%
ALCL,ALK-	26%
ALCL,ALK+	8%
NKTCL	10%
Extranodal PTCLs, other	4%
Unclassifiable T-cell	2%

Asia

PTCL-NOS	28%
AITL	17%
ALCL,ALK-	5%
ALCL,ALK+	5%
NKTCL	30%
Extranodal PTCLs, other	9%
Unclassifiable T-cell	6%

Major Lymphoma Subtypes by Geographic Region (%)

Subtype	North America		Europe		Asia		South America	
	ITCLP	TCP	ITCLP	TCP	ITCLP	TCP	ITCLP	TCP
PTCL-NOS	34.4	35,5	34.3	36,7	22.4	28,6	-	41,4
Angioimmunoblastic	16.0	20,9	28.7	20,9	17.9	16,6	-	8,0
ALCL, ALK pos	16.0	9,3	6.4	9,2	3.2	4,6	-	7,7
ALCL, ALK neg	7.8	13,1	9.4	14,1	2.6	4,6	-	26,4
NK/T-cell	5.1	8,1	4.3	7,8	22.4	30,3	-	10,0
ATLL	2.0	-	1.0	-	25.0	-	-	-
EATL	5.8	2,5	9.1	6,2	1.9	2,9	-	3,8
Hepatosplenic	3.0	3,7	2.3	1,6	0.2	1,7	-	0,4
Primary cutaneous ALCL	5.4	-	0.8	-	0.7	-	-	-
Subcutaneous panniculi.	1.3	2,2	0.5	1,1	1.3	3,4	-	-

Major Lymphoma Subtypes by South American Country (N=261)

Subtype	South America All (N=261) N	South America All (N=261) %	Chile (N=141) %	Brazil (N=64) %	Argentina (N=38) %	Uruguay (N=18) %
PTCL-NOS	108	41,4	46,1	28,1	42,1	50,0
Angioimmunoblastic	21	8,0	7,1	12,5	7,9	0
ALCL, ALK pos	20	7,7	5,0	12,5	13,2	0
ALCL, ALK neg	69	26,4	29,1	23,4	26,3	16,7
NKTCL	26	10,0	7,1	18,8	5,3	11,1
EATL	10	3,8	3,5	0	2,6	22,2
Hepatosplenic	1	0,4	0	1,6	0	0
Unclassifiable T-cell	6	2,3	2,1	3,1	2,6	2,3

Database Completeness

67%

Registration (All)	934
• Baseline	99%
• Clinical Data	86%
• Laboratory	79%
• Easy Stage	76%
• Planned Approach	86%
Therapy	1020
Adequate follow-up	847

73%

61%

41%

Cases completed	574

Patients characteristics [1]

Parameter		N_{TOT}		
Median age (yrs)		1389	56 (18-90)	
			N	%
Age ≥60 yrs		1389	616	**44%**
Gender (Male)		1389	835	**60%**
ECOG >1		1201	312	**26%**
B-symptoms		1201	594	**49%**
Discomfort disease-related		1201	868	**72%**
IPI		**993**		
LOW-LOW/INTERMEDIATE	0-2		593	**60%**
INTERMEDIATE/HIGH-HIGH	3-5		400	**40%**
PIT		**933**		
LOW-LOW/INTERMEDIATE	0-1		560	**60%**
INTERMEDIATE/HIGH-HIGH	2-4		373	**40%**

Patients characteristics [2]

Parameter	N_{TOT}	N	%
Stage III-IV	1058	710	**67%**
Nodal only disease	1058	266	**25%**
Bulky disease (≥ 10 cm)	1058	65	**6%**
Number of extranodal sites >1	1058	320	**30%**
BM involvement	951	198	**21%**
LDH > ULN	1010	492	**49%**
HB ≤ 11 g/dL	1080	330	**31%**
Platelets ≤ 150K/mm^3	1079	196	**18%**
Lymphocytes ≤ 1000/mm^3	1047	402	**38%**
Monocytes > 800/mm^3	994	241	**24%**
Beta2-microglobulin > ULN	591	386	**65%**
CRP > ULN	572	403	**70%**

Main Patients characteristics & Treatment by geographic area (N=1,389; Tx N=1,020)

	South America (N=261)		USA (N=321)	Europe (N=632)	Asia (N=175)
	N	%	%	%	%
Median age (yrs)	53 (18-88)		56 (18-88)	58 (18-90)	54 (18-89)
Age ≥60 yrs	92	35,2	45,5	50,3	34,3
Sex (Male)	150	57,7	56,7	63,1	59,4
ECOG >1	115	45,6	18,1	23,8	13,9
B-symptoms	151	59,9	46,0	50,0	36,1
Stage III-IV	134	58,3	68,2	73,2	60,0
NES >1	60	26,1	25,6	34,3	29,7
Therapy with curative intent	184	85,2	91,8	92,9	98,1
Chemotherapy +/- RT	182	84,2	89,1	91,5	95,4
Anthracycline	159	87,4	44,2	79,6	55,8
Etoposide	3	1,6	23,9	1,4	25,9
	11	6,0	28,8	11,3	8,8
Both					
HDT consolidation/salvage	5/11	2/5	13/9	8/16	6/17

Main Patients characteristics & Treatment by South American Country (N=261)

	South America All (N=261)		Chile (N=141)	Brazil (N=64)	Argentina (N=38)	Uruguay (N=18)
	N	%	%	%	%	%
Median age (yrs)	53 (18-88)		53 (18-83)	50 (21-88)	54 (21-88)	57 (36-81)
Age ≥60 yrs	92	**35,2**	**34,0**	**31,1**	**42,1**	**44,4**
Sex (Male)	150	**57,7**	**64,5**	**48,4**	**44,7**	**61,1**
ECOG >1	115	**45,6**	**60,3**	**13,6**	**40,0**	**47,1**
B-symptoms	151	**59,9**	**60,3**	**55,9**	**57,1**	**76,5**
Stage III-IV	134	**58,3**	**57,9**	**61,1**	**53,1**	**63,6**
NES >1	60	**26,1**	**24,1**	**29,6**	**28,1**	**27,3**
Therapy with curative intent	184	**85,2**	**80,8**	**93,5**	**93,9**	**75,0**
Chemotherapy +/- RT	182	**84,2**	**80,8**	**89,1**	**94,0**	**75,0**
Anthracycline	159		**97,0**	**78,0**	**71,0**	**77,8**
Etoposide	3		**0**	**4,9**	**3,2**	**0**
Both	11		**2,0**	**12,2**	**9,7**	**11,1**
HDT consolidation/salvage	5/11	**2/5**	**0/0**	**4/17**	**9/6**	**0/8**

PTCL-NOS: Main patient characteristics

Parameter	Vose et al 2008 International T-Cell Lymphoma Project	T-Cell Project
	N=340	N= 504
Median Age (years)	60 years	59 years
Male Gender	66 %	60 %
Stage III/IV	69 %	77 %
Marrow positive	22 %	23 %
IPI 0/1	28 %	23 %
IPI 2/3	57%	59 %
IPI 4/5	15 %	18 %

AITL: Main patient characteristics

Parameter	Vose et al 2008 International T-Cell Lymphoma Project	T-Cell Project
	N=243	N=249
Median Age (years)	65 years	64 years
Male Gender	56%	60 %
Stage III/IV	89%	90%
Marrow positive	29%	30%
IPI 0/1	14%	19%
IPI 2/3	59%	54%
IPI 4/5	28%	27%

NKTCL: Main patient characteristics

Parameter	Vose et al 2008 International T-Cell Lymphoma Project		T-Cell Project	
	N=127		N=142	
	Nasal N=92	ExtNas N=35	Nasal N=36	ExtNas N=106
Median Age (years)	52 yr	44 yr	55 yr	51 yr
Male Gender	64 %	68 %	72 %	64 %
Stage III/IV	27 %	69 %	16 %	29 %
Marrow positive	10 %	18 %	0 %	7 %
IPI 0/1	51 %	26 %	70 %	54 %
IPI 2/3	47 %	57 %	30 %	35 %
IPI 4/5	2 %	17 %	0 %	7 %

ALCL: Main patient characteristics

Parameter	Vose et al 2008 International T-Cell Lymphoma Project		T-Cell Project	
	N=159		N=324	
	ALK+ N=87	ALK- N=72	ALK+ N=116	ALK- N=208
Median Age (years)	34 yr	58 yr	38 yr	54 yr
Male Gender	63 %	61 %	58 %	62 %
Stage III/IV	65 %	58 %	73 %	60 %
Marrow positive	12 %	7 %	9 %	7 %
IPI 0/1	49 %	41 %	47 %	41 %
IPI 2/3	37 %	44 %	49 %	44 %
IPI 4/5	14 %	15 %	4 %	15 %

EATL: Main patient characteristics

Parameter	Vose et al 2008 International T-Cell Lymphoma Project	T-Cell Project
	N=62	N=62
Median Age (years)	61 years	59 years
Male Gender	53 %	63 %
Stage III/IV	69 %	59 %
Marrow positive	3 %	12 %
IPI 0/1	25 %	37 %
IPI 2/3	63 %	48 %
IPI 4/5	13 %	14 %

Hematological ONCOLOGY

Pitfalls and major issues in the histologic diagnosis of Peripheral T-cell Lymphomas: results of the central review of 573 cases from the T-Cell Project, an International, Cooperative Study.

Monica Bellei[1], Elena Sabattini[2], Emanuela Anna Pesce[1], Young-Hyeh Ko[3], Won Seog Kim[4], Maria Elena Cabrera[5], Virginia Martinez[6], Ivan Dlouhy[7], Roberto Pinto Paes[8], Tomas Barrese[8], Josè Vassalo[9], Vittoria Tarantino[1], Julie Vose[10], Dennis Weisenburger[11], Thomas Rüdiger[12], Massimo Federico[1], Stefano Pileri[13,14].

Pitfalls and major issues in the histologic diagnosis of Peripheral T-cell Lymphomas: results of the central review of 573 cases from the T-Cell Project, an International, Cooperative Study.

- A diagnosis of PTCL or NKTCL was confirmed in 461 of the cases (80.4%); 49 additional cases (8.5%) were misclassified locally and reclassified by central reviewers with a different subtype among those eligible for the study.
- The subtypes for which the major difficulties in correctly diagnosing and classifying the disease by local pathologists were PTCL-NOS and ALCL, ALK-.

Pitfalls and major issues in the histologic diagnosis of Peripheral T-cell Lymphomas: results of the central review of 573 cases from the T-Cell Project, an International, Cooperative Study.

- The results of the review confirm that these neoplasms can be easily misclassified or misdiagnosed in the daily practice, being a correct diagnosis still a very critical issue that needs a painstaking attention.
- The T-Cell project experience highlights that expert hematopathology review with the application of adequate diagnostic algorithms is essential when dealing with these tumors, since a misdiagnosis could have a crucial impact on a correct treatment choice and consequently on patient care.

28-Mar-2016

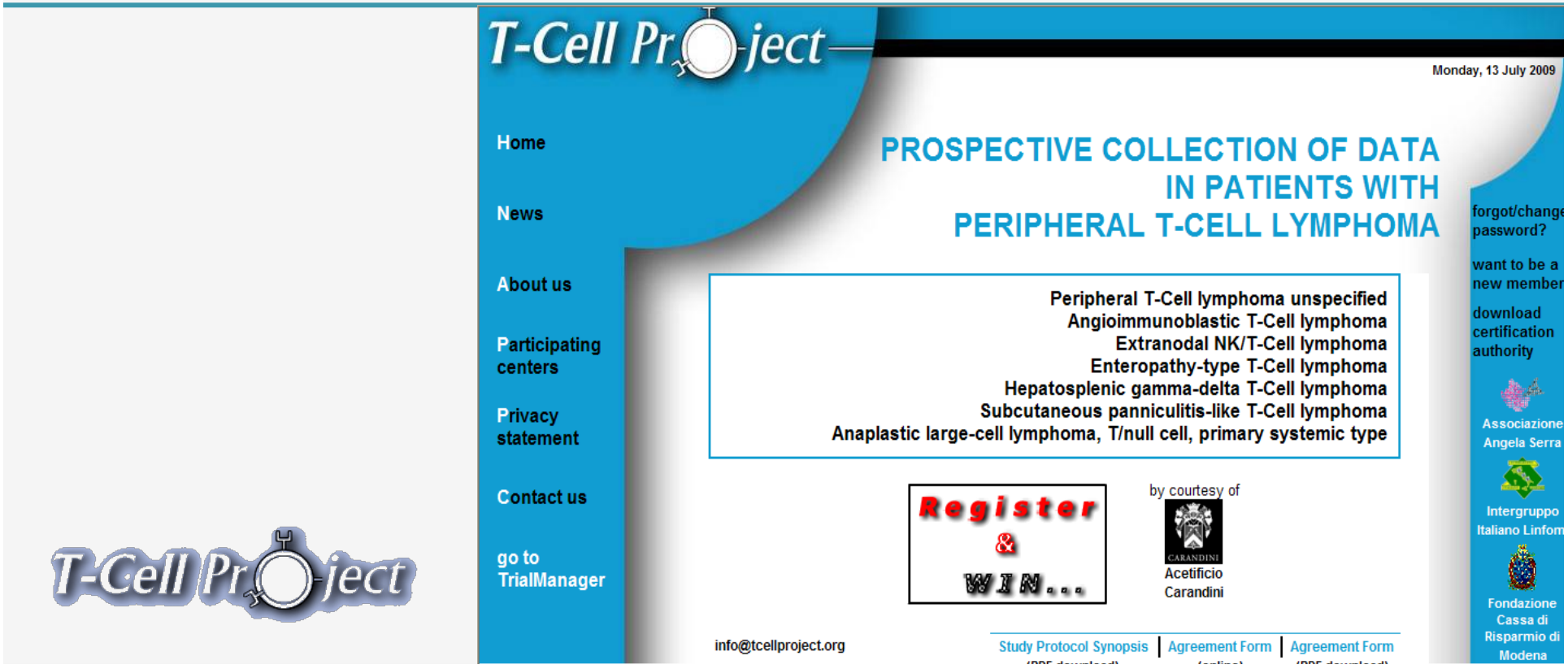
Dear Dr. Bellei,

Manuscript ID HON-16-0043 entitled "Pitfalls and major issues in the histologic diagnosis of Peripheral T-cell Lymphomas: results of the central review of 573 cases from the T-Cell Project, an International, Cooperative Study." which you submitted to Hematological Oncology, has been reviewed.

The referees have recommended publication, but also suggest some minor revisions to your manuscript.

Comprehensive Oncology Measures for PeripheraL T-cEll Lymphoma TrEatment The "COMPLETE" Registry

Prospective, Longitudinal, Multinational Registry of Patients with Newly Diagnosed Peripheral T-Cell Lymphoma



Curr Hematol Malig Rep
DOI 10.1007/s11899-015-0291-0

T-CELL AND OTHER LYMPHOPROLIFERATIVE MALIGNANCIES (P PORCU, SECTION EDITOR)

The Value and Relevance of the T Cell Lymphoma Registries and International Collaborations: the Case of COMPLETE and the T-Cell Project

Monica Bellei[1] · Chadi Nabhan[2] · Emanuela Anna Pesce[1] · Luana Conte[3] · Julie M. Vose[4] · Francine Foss[5] · Massimo Federico[1]

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COMPLETE & TCP: Sybtypes distribution (%)

13-ICML
13th International Conference on Malignant Lymphoma
Palazzo dei Congressi, Lugano, Switzerland, June 17-20, 2015

Bellei M *et al* Abs #231
Nabhan C *et al* Abs # 232

Diagnosis	2010-2014	2006-2014
Baseline data (N)	395	819
Therapy data (N)	361	754

	≤ 60 yrs		>60<70 yrs		≥ 70 yrs		*P*	
	207	**462**	**88**	**168**	**100**	**189**		
PTCL-NOS	**29**	**32**	**40**	**42**	**38**	**47**	***.002****	***.001****
AITL	**10**	**12**	**25**	**18**	**20**	**28**		
ALCL, ALK pos	**9**	**11**	**4**	**2**	**1**	**1-2**		
ALCL, ALK neg	**11**	**17**	**9**	**15**	**12**	**9**		
NKTCKL	**14**	**14**	**9**	**16**	**5**	**12**		
Other	**27**	**13**	**12**	**13**	**24**	**8**		

** PTCL-NOS vs other subtypes*

COMPLETE & TCP: Patient characteristics (%)

13-ICML
13th International Conference on Malignant Lymphoma
Palazzo dei Congressi, Lugano, Switzerland, June 17-20, 2015

Bellei M *et al* Abs #231
Nabhan C *et al* Abs # 232

	≤ 60 yrs		>60<70 yrs		≥ 70 yrs		*P*	
	207	462	88	168	100	189		
Male gender	61	61	65	68	63	57	*.81*	*.09*
B-symptoms (presence)	52	50	42	54	43	44	*.16*	*.21*
Stage III-IV	71	66	72	71	66	75	*.55*	*.06*
Sites of disease								
Nodal	60	72	66	74	58	81	*.51*	***.054***
Extranodal	62	74	56	76	58	72	*.58*	*.65*
LDH > ULN	<1	48	0	48	4	48	***.02***	*.99*

COMPLETE & TCP: Treatment characteristics (%)

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	≤ 60 yrs		>60<70 yrs		≥ 70 yrs		*P*	
	189	426	78	156	94	172		
Primary intent of Tx							***<.0001***	***<.0001***
Curative	94	96	89	90	69	87		
Palliation	6	4	12	10	31	13		
First line TX approach								
CHT alone	58	67	58	73	64	75	*.58*	*.13*
CHT +HDT consolidat.	23	10	22	5	3	1	***<.0001***	***<.0001***
CHT + RT consolidat.	6	17	8	9	7	9	*.90*	***.008***
Local RT alone	1	2	1	3	9	2	***.002***	*.76*
Observation /BSC	2	4	34	10	10	13	***.02***	***.02***
Other	10	10	9	9	8	8		

COMPLETE & TCP:
Type of chemoherapy (%)

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	≤ 60 yrs		>60<70 yrs		≥ 70 yrs	
	189	426	78	156	94	172
CHOP/CHOP-like	26	52	34	54	33	54
CHOEP/CHOEP-like	20	9	17	13	13	3
Gemcitabine-based	4	0	1	1	8	2
Platinum- based	6	3	3	2	1	1
Ifosfamide-based	8	6	4	1	0	1
Other	37	30	41	29	44	39

COMPLETE & TCP: Outcome

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	≤ 60 yrs		>60<70 yrs		≥ 70 yrs		*P*	
	189	426	78	156	94	172		
2-yr OS (%)		60		55		40		*<.0001*
5-yr OS (%)		51		38		24		
Median survival (mos)	**45.3**		**41.9**		**26.4**			

Cox modeling predictors of OS

		HR	*P*		HR	*P*
Better survival *HDT consolidation*		**0.19** ***95%CI 0.09-0.42***	*<.0001*		**0.50** ***95%CI 0.29-0.85***	*.01*
Inferior survival *Stage III-IV* *Age*		**3.4** ***95%CI 1.91-6.20***	*<.0001*		**3.0** ***95%CI 1.45-6.22*** **1.12** ***95%CI 1.04-1.20***	*<.003* *<.004*

Conclusions

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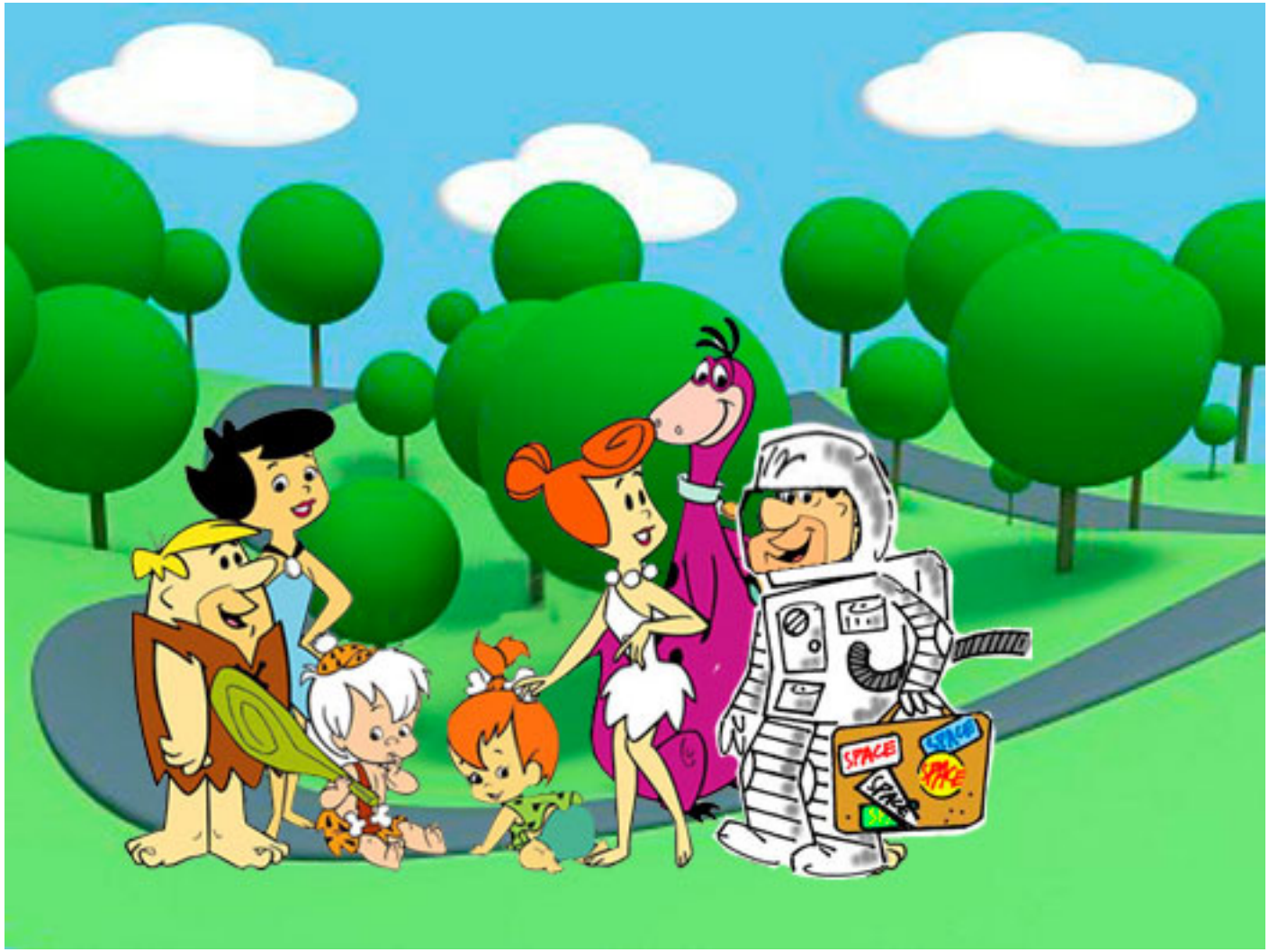
- Patients aged ≥ 70 yrs are more likely to receive non-curative intent TX
- HDT was an independent predictor of better OS
- Stage III-IV (both studies) and Age (TCP) are independent predictor of inferior OS
- Optimal treatment, especially for the elderly subset is still a relevant unmet need, more efforts to define better strategies are urgent

Conclusions

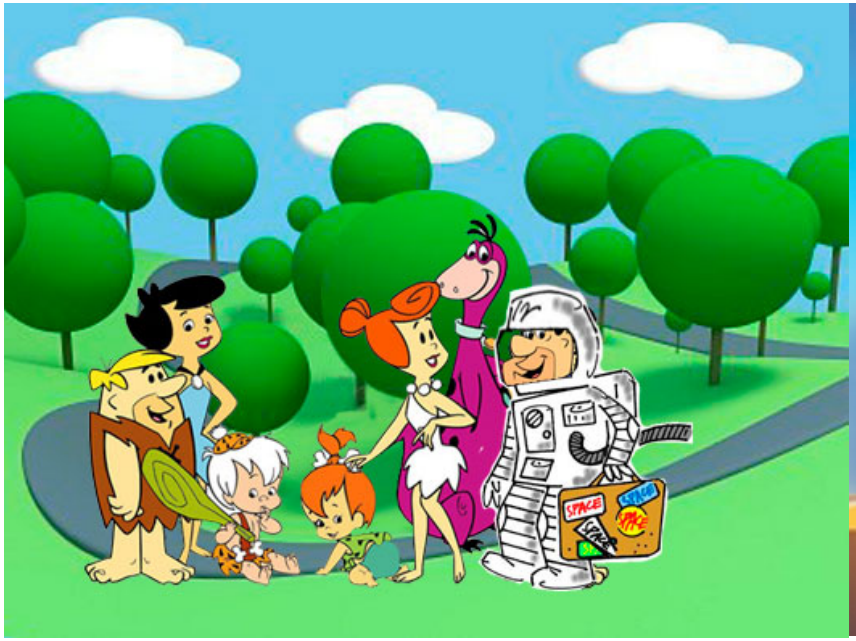
- PTCL is a very heterogeneous lymphoma – many subtypes
- Treatment remains challenging
- Retrospective and prospective information very similar patient populations
- Looking forward to new information and therapies!

…a step forward…



Next steps

- Continue registration reaching a total of at least 2,000 assessable cases
- Create an international tissue catalogue including FFPE samples as well as frozen tissue, accessible to research groups with a solid reputation in studying PTCLs
- Activate new sites/areas
  - ✓ Concord Hospital, Sidney (Judith Trotman)
  - ✓ AGMT, Austria - Study Group of Medical Tumour Therapy (Richard Greil, Lukas Weiss)
  - ✓ ACHO, Colombia - Colombian Association of Hematology and Oncology (Virginia Abello Polo)



THANK YOU