



QUALITY OF LIFE: A NURSING PERSPECTIVE

Quality of Life (QoL) is important for all people. This measure is at risk for being significantly altered when a cancer diagnosis is rendered. Quality of life significantly impacts not only the patient diagnosed with a disease, but also the people closest to that individual: family members, caregivers, and friends. Making an effort to improve quality of life is extremely important in a patient's life and helping healthcare providers better understand how QoL affects people is vital in addressing it as part of the overall treatment plan. Several studies have been conducted looking at self-reported impacts of cutaneous lymphoma on quality of life using several types of assessment tools.

There have been a number of important studies looking at various aspects of Quality of Life in CTCL. In 2005, Demierre and colleagues at Boston University, in collaboration with the Cutaneous Lymphoma Foundation, devised a health-related quality of life survey evaluating patients' perspectives regarding the impact of cutaneous lymphoma and its treatment on lifestyle, occupation, and social-emotional wellbeing. Of the respondents, whom were predominantly early stage disease patients, 94% reported being worried about the seriousness of their disease, with a staggering 80% reporting that they were worried about dying. Other concerns that were derived and reported from the study included both physical symptoms as well as functional impacts, including negative effects on sleep, self-perceived physical attractiveness, and financial burdens.



The first international cutaneous lymphoma health-related QoL survey was conducted using a Skindex 29 questionnaire and focused on three main areas of QoL including emotions (worried, depressed, shame); symptoms (itching, burning, pain); and function (ability to work, sleeping, relationships) (Molloy et al., 2019). The findings indicated that decreased QoL was linked with the extent of the skin disease, stage, and blood involvement. Patients with later stage disease indicated that their QoL was more negatively impacted. In addition, women reported overall worse QoL than men with decreased QoL in emotional and symptom subscales. This study highlighted the importance of increased awareness of QoL issues among healthcare providers in helping to alleviate some of the burden

associated with a cancer diagnosis. (Molloy et al., 2019).

A 2018 Lymphoma Coalition Patient survey looked at 6,631 respondents, 203 of which had cutaneous lymphoma. This study hinted at the lack of communication with doctors about emotional issues. Over 40% of patients reported not having communicated at all any of their emotional burdens with their doctors.

A patient's quality of life is extremely important, as is the QoL of those closest to them. As caregivers are often wrapped up in their roles as a care provider, their own QoL is often overlooked.

Quality of Life...continued on page 9

2020 Issue 2

From the President and the Chief Executive Officer	3
Understanding the Research: Decoding Cutaneous Gamma Delta T Cell Lymphomas ...	4
A Note From The Editor	5
4th World Congress of Cutaneous Lymphomas, February 12-14, 2020, Barcelona, Spain	6

FLASH Study Demonstrates Increased Efficacy with Continued Treatment in Patients with Cutaneous T-Cell Lymphoma	8
Get Your Move On!	10
In Memory	10
Frequently Asked Questions	11

What Is Cutaneous Lymphoma?

Cutaneous lymphomas are cancers of lymphocytes (white blood cells) that primarily involve the skin. Classification is based on lymphocyte type: B-lymphocytes (B-cell) or T-lymphocytes (T-cell). Cutaneous T-cell lymphoma (CTCL) is the most common type of cutaneous lymphoma that typically presents with red, scaly patches or thickened plaques of skin that often mimic eczema or chronic dermatitis. Progression from limited skin involvement is variable and may be accompanied by tumor formation, ulceration and exfoliation, complicated by itching and infections. Advanced stages are defined by involvement of lymph nodes, peripheral blood, and internal organs. 

Cutaneous Lymphoma Foundation is a 501(c)(3) non-profit organization. Donations are tax deductible to the extent allowed by law.

BOARD OF DIRECTORS

OFFICERS

Laurel Carlson	President
David Elefant	Vice President
Jeff Ward	Treasurer
Marianne Tawa, RN, MSN, ANP	Secretary

DIRECTORS

Steven Horwitz, MD	Director
Youn Kim, MD	Director
Lauren Pinter-Brown, MD	Director
Michael W. Young	Director
Susan Thornton	Chief Executive Officer

RESEARCH ADVISORY COUNCIL

Pierluigi Porcu, MD (Co-Chair)	Thomas Jefferson University
Christine Eischen, PhD (Co-Chair)	Thomas Jefferson University
Jaehyuk Choi, MD, PhD	Northwestern University
Alejandro Gru, MD	University of Virginia
Bradley Haverkos, MD, MPH	University of Colorado
Steven Jones, MD	Patient
Michael Khodadoust, MD, PhD	Stanford University
Stuart Lessin, MD	KGL Skin Study Center
Laura McGirt, MD	University of North Carolina
Anjali Mishra, PhD	Sidney Kimmel Cancer Center
Alison Moskowitz, MD	Memorial Sloan Kettering Cancer Center
Christopher Shipp	Patient

MEDICAL ADVISORY COUNCIL

Ellen Kim, Chair, MD (Chair)	University of Pennsylvania
Wei Ai, MD	University of California San Francisco
Kim Bohjanen, MD	University of Minnesota
Francine Foss, MD	Yale University
Richard Hoppe, MD	Stanford Cancer Center
Erick Lansigan, MD	Dartmouth-Hitchcock Medical Center
Cecilia Larocca, MD	Dana-Farber/Brigham and Women's Cancer Center
Leora Lowenthal, LICSW, OSW-C, MPA	Beth Israel Deaconess Medical Center
Sue McCann, MSN, RN, DNC	University of Pittsburgh
Amy Musiek, MD	Washington University School of Medicine
Steve Rosen, MD, FACP	City of Hope
Debjani Sahni, MD	Boston University
Michi Shinohara, MD	University of Washington
Jasmine Zain, MD	City of Hope

MEDICAL ADVISORY COUNCIL EMERITUS ADVISORS

Madeleine Duvic, MD	University of Texas MD Anderson
Lars French, MD	University Hospital Zurich
Robert Knobler, MD	Medical University of Vienna
Thomas Kupper, MD	Dana-Farber/Brigham and Women's Cancer Center
Liliane LaRoche, MD	Hospital Avicenna
David Ramsay, MD	New York University School of Medicine
Alain Rook, MD	University of Pennsylvania
Martin Weinstock, MD, PhD	Brown University
Sean Whittaker, MRCP	Guy's and St. Thomas' Hospital

STAFF

Holly Priebe	Chief Operating and Financial Officer
Hilary Romkey	Program Manager
Debra Van Zegeren	Information Technology Manager
Susette Arnot	Administrative Assistant

FORUM

The newsletter of the Cutaneous Lymphoma Foundation
ALL RIGHTS RESERVED

Cutaneous Lymphoma Foundation
PO Box 374
Birmingham, MI 48012-0374
telephone: (248) 644-9014
fax: (248) 644-9014
email: info@clfoundation.org
www.clfoundation.org

Forum is published by the
Cutaneous Lymphoma Foundation.
Editor: Hilary Romkey
Layout & Design: Art/Design Group, Ltd.

Disclaimer

The Cutaneous Lymphoma Foundation does not endorse any drugs, treatments or products reported in this newsletter. Information is provided for informational purposes only. Because the symptoms and severity of cutaneous lymphoma vary among individuals, the Cutaneous Lymphoma Foundation recommends that all drugs and treatments be discussed with the reader's physician(s) for proper evaluation, treatment and medical care.

The Cutaneous Lymphoma Foundation's patient educational newsletter, **Forum**, has been made possible in part thanks to the following generous supporters:



FROM THE BOARD PRESIDENT

Laurel Carlson



Hello,

I hope this newsletter finds you and your family in good health as we continue to live with the effects of the global pandemic. I also hope that, in lieu of our in-person events, you are taking advantage of our many online programs. Please make sure that you read the emails and publications sent to you from the Cutaneous Lymphoma Foundation

and check our Facebook pages for updates and advice as things frequently change. You know, as the saying goes, please listen carefully as our menu options have recently changed.

Research is the focus of this issue. We, at the Foundation, have been conducting a lot of research of our own lately. The short surveys that we request you to complete at a program's conclusion and the focus groups we have surveyed are providing us with important data for determining and meeting the needs of our community. We value each of your opinions and hope that you will not hesitate to provide us with any feedback which will help us improve the services that we deliver to you.

Like most organizations, our Foundation has a vision and a mission. Last August, our staff and Board of Directors began

the development of our three-year strategic plan, which included revising both our vision and mission statements. While our vision simply stated is "A life free of cutaneous lymphoma," our mission outlines what steps we must take in order to achieve this. We strive to "Eliminate the burden of cutaneous lymphoma by: promoting awareness, providing education, advancing patient care, and fostering research." The Foundation originally did not include research support as part of their focus, but today our mission statement specifically includes fostering research as a way to help eliminate our disease's impact. To facilitate this, we created our Research Advisory Council (RAC) to advise and recommend how we can best foster research that will benefit our patient community. The RAC is a committed group of distinguished scientists, accomplished clinical experts, leaders of cutaneous lymphoma research, and patient advocates who volunteer their time and talent to develop and expand the research programs offered and supported by the Cutaneous Lymphoma Foundation.

Of course, we would not be able to offer this support without your generous donations. Please know that all donations, large and small, are appreciated and help us to move forward with all parts of our mission, including research. Thank you for your support.

Take care and stay safe,

FROM THE CHIEF EXECUTIVE OFFICER

Susan Thornton

"I've learned that no matter what happens, or how bad it seems today, life does go on, and it will be better tomorrow."

— Maya Angelou

Here we are in the summer of 2020. Our world has been turned upside down. And yet, we continue to put one foot in front of the other, day-by-day. My heart goes out to everyone, no matter where you may find yourself as you read this; it's been a rough ride all the way around. And yet, I believe the Foundation has found a way through; a way to continue to serve you,

our precious community, as best as we can.

In this summer issue we focus on research and the good news that comes from the work being done around the world; work to understand this group of rare skin lymphomas, to find new treatments, to find new ways of combining treatments that can make a difference in someone's life who is living with it. I am humbled and honored to know many of these brilliant scientists, clinicians, and investigators, who have dedicated their life's work to this disease and to all of us.



From the CEO...continued on page 9

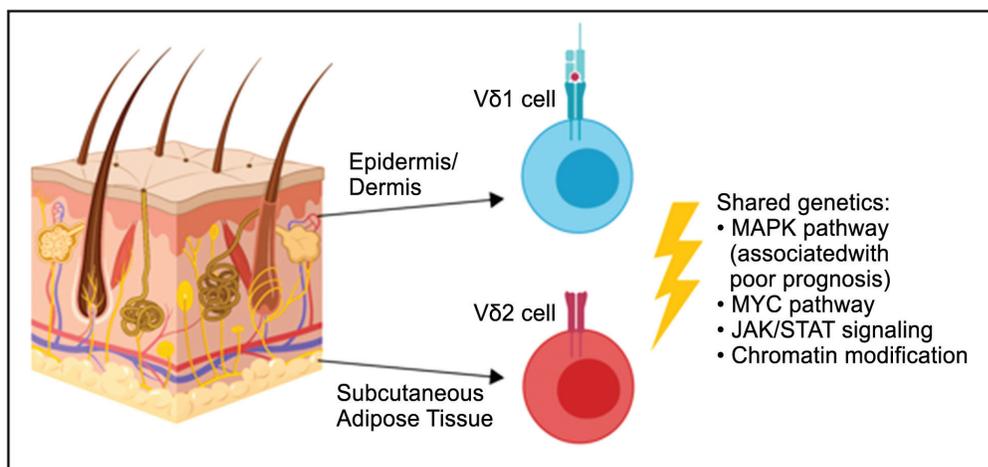
Understanding the Research: Decoding Cutaneous Gamma Delta T Cell Lymphomas

Cutaneous lymphomas are a heterogeneous collection of cancers. Each disease requires a distinct approach to disease diagnosis, staging, and treatment. Unfortunately, some of these cancers are poorly understood. Without this fundamental knowledge about disease origins and disease behaviors, we do not have a data-driven framework to justify clinical decisions. Moreover, it is difficult to rationally design new groundbreaking therapies. The Choi lab at Northwestern (<http://choilaboratory.northwestern.edu>) is dedicated to illuminating the molecular and cellular bases of skin lymphomas. We are confident that a deep understanding of disease biology is the key to unlocking novel, potentially curative treatment strategies.

There is a special subtype, the gamma delta T cell lymphoma, which can be highly aggressive. Unfortunately, little is known about this cancer type, stymieing medical progress in this area. To better understand these cancers, Dr. Jaehyuk Choi and two talented medical students, Jay Daniels and Peter Doukas, collaborated with CTCL experts around the world, including Dr. Joan Guitart, Dr. Alejandro Gru, and others. Together, they assembled a large collection of cases to which they applied cutting edge molecular approaches and serendipitously found new knowledge that will hopefully provide a framework pivotal for improving the way the disease is diagnosed, staged, and treated.

The first important take-home finding is that the disease is heterogeneous. For example, some patients have prolonged indolent disease and require only skin-directed therapy. Others initially have prolonged indolent disease but then progress into an aggressive subtype. Still others present initially with aggressive disease that requires systemic therapy right away. Moreover, some but not all patients develop potentially life-threatening multi-organ inflammatory syndromes called hemophagocytic lymphohistiocytosis (HLH). For others, the disease spreads into the internal organs such as the stomach. How or why these patients are different from one another was not immediately obvious.

The second important take-home finding is that the skin



Schematic of the pathogenesis of gamma delta cutaneous T cell lymphomas

compartment from which the lymphoma arises is clinically and biologically important. We found that these gamma delta cutaneous T cell lymphomas or $\gamma\delta$ CTCLs are centered in one of three layers of skin, the superficial epidermis, the intermediate dermis, or the deep subcutaneous fat. The depth of the infiltrate appears to determine clinical heterogeneity. Superficial lymphoma infiltrates lead to thin patches that can be indolent. Deeper lymphoma infiltrates in the dermis and the fat can lead to thick tumor nodules that can be aggressive.

By applying whole genome sequencing to these cases, the lab found cellular and genetic explanations for disease heterogeneity. We found that each of the $\gamma\delta$ cutaneous T cell lymphomas arise from a compartment-specific skin-resident $\gamma\delta$ T cell. Epidermal $\gamma\delta$ CTCLs arise from epidermal $\gamma\delta$ T cells. Dermal $\gamma\delta$ CTCLs arise from dermal $\gamma\delta$ T cells, and panniculitic $\gamma\delta$ CTCLs arise from $\gamma\delta$ T cells resident in the subcutaneous fat. The epidermal and dermal $\gamma\delta$ CTCLs are derived from a V δ 1 $\gamma\delta$ T cell. The panniculitic $\gamma\delta$ CTCL is derived from the V δ 2 $\gamma\delta$ T cell.

The third important take-home finding is that the molecular differences between the cells of origin contributes to patient-to-patient disease heterogeneity. V δ 1 lymphomas have a better prognosis than V δ 2 lymphomas. In part, this is because all of the indolent $\gamma\delta$ CTCLs with or without aggressive transformation are derived from V δ 1 cells. Moreover, consistent with the trafficking patterns of other V δ 1 cells, the V δ 1 lymphomas are the only ones that spread to the gastrointestinal tract, e.g. to the stomach. In contrast, the V δ 2 lymphomas are universally aggressive, are more likely to be

ulcerated, are more inflammatory, and have a higher risk of cancer-associated syndromes such as HLH.

Lastly, we identified mutations that support future clinical trials. These include targetable mutations in two clinically relevant pathways, the JAK/STAT pathway and the MAPK pathway. Despite being a relatively uncommon cancer, $\gamma\delta$ CTCLs may be treated with drugs initially developed for other cancers with similar cancer mutations. Lastly, a subset of gamma delta CTCL driver genes, KRAS, NRAS, and

MAPK1, appear to be a clinically useful biomarker. They portend a worse prognosis with current treatment strategies. Thus, these mutations may justify using more aggressive disease earlier in the disease course.

In sum, we are excited to have made clinically relevant biological discoveries that support new ways at looking at and treating these aggressive cancers. We plan on building on these discoveries to bring new, potentially curative therapies to our patients.



Jaehyuk Choi Joan Guitart Jay Daniels Peter Doukas

Jaehyuk Choi, MD, PhD
Northwestern University Feinberg School of Medicine

Joan Guitart, MD
Northwestern University Feinberg School of Medicine

Jay Daniels

Peter Doukas

A NOTE FROM THE EDITOR...

Hilary Romkey

The past few months have been a whirlwind for all of us; there has been much uncertainty surrounding many aspects of our lives, and the Cutaneous Lymphoma Foundation has been no exception. With the unfolding events surrounding COVID-19, we have shifted our programs to a virtual platform in an effort to continue to serve our community during this time.

In an effort to better understand the needs of our constituents, we conducted a survey through a focus group to provide us with feedback on desired content, as well as the method in which you wish to receive this information. Our hope is to continue to shift our programs to meet the needs of the people we are serving – your feedback is always welcome and appreciated as we exist to serve YOU.

The results we received from the survey indicated that our community is most interested in hearing about the following:

- Disease Specific Information – 36%
- Treatment Information – 29%
- Patient Stories and/or Peer-to-Peer Experiences – 17%
- Research Information and/or Updates – 10%
- Health and Wellness – 4%
- Other – 4%

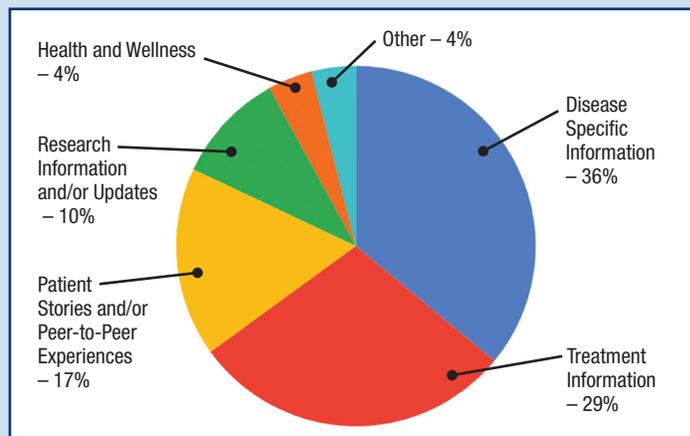
Topics will be presented in the most appropriate way to discuss the information and allow for both informal discussions and formal presentations. The majority of our virtual programs will be presented in the following ways:

Webinars: An educationally themed program with one or more presentations from medical professionals. Each webinar will address a specific topic in a formal setting.

Panel Discussions: A panel of participants holding a discussion, sharing perspectives on the topic. Audience members are engaged in the conversation through question and answer opportunities.

Facebook Live Events: Focus on topics including health and wellness, emotional support, nutrition, exercise, and more. Delivered with an opportunity for the community to engage with questions in a live setting.

We hope you find our programs educational and inspiring. As always, please let us know how we can best serve you. Suggestions are always welcome: hilary@clfoundation.org.



4th World Congress of Cutaneous Lymphomas, February 12-14, 2020, Barcelona, Spain

MEETING HIGHLIGHTS

The 4th World Congress of Cutaneous Lymphomas (4WCCL) was held in Barcelona in February, just under the wire before the COVID-19 virus shut down travel and meetings. A diverse, international group of more than four hundred cutaneous lymphoma experts attended. Every four years, this global meeting brings together a wide array of clinicians and researchers to discuss recent discoveries and insights covering all aspects of this complex, rare disease.

The meeting showcased 150 oral presentations, 84 oral poster presentations, and several keynote lectures over three days. All specialties were represented with in-depth discussions around a wide variety of topics from prognostic indicators, immunology, biomarkers, epigenetics, genomics, treatments, clinical trials, and quality of life. Although the oral presentations were short, 8-9 minutes long with a few minutes for questions, the networking and collaboration that occurred throughout the meeting showed the commitment and passion of this incredible group of people who have dedicated their time, energy, and careers to helping patients. It was exciting to see many of our Young Investigator awardees and CLARIONS/Catalyst research grant recipients sharing their work. While there is still much work to be done, it is inspiring to see the forward momentum.

The Cutaneous Lymphoma Foundation team had the privilege of attending, listening first hand to the vast array of scientific presentations. A few highlights are shared here. Additional reports are available on the website for those who have an interest in learning more.

The opening session was a lecture from Dr. Elias Campo, Clinical Director of the Biomedical Diagnostic Centre of the Hospital Clinic at the University of Barcelona. Dr. Campo talked about how different the various types of lymphomas are and the progress made since the basic research began in 1975. He pointed out that cutaneous lymphoma classifications have continued to evolve, adding more subtypes as the technology and science has progressed. Today, the task is integrating clinical information with the scientific disease information to lead to better prognostic indicators, more predictive treatment outcomes, and identification of new therapeutic targets.

The dedication and passion for this work from everyone in attendance was inspiring. Understanding the disease mechanisms and why treatments work or stop working still elude the experts. However, much progress has been made in the last few years. It's thrilling to see the number of young researchers, clinicians, and investigators joining the field. There is so much hope!

A shortlist of significant takeaways from the sessions:

Mycosis Fungoides (MF): 65-85% of all cutaneous T-cell lymphomas are MF. Early diagnosis continues to be challenging due to the absence of definitive diagnostic criteria. The quest for diagnostic markers continues, primarily to determine markers that could be used in diagnosing early stage. Although more work is needed to understand what is going awry in the T-cells in early-stage disease, some promising markers were discussed.

Folliculotropic Mycosis Fungoides (FMF): Outcomes from an international study were shared. The study showed that the clinical presentation of this rarer subtype is quite variable. However, new insights conclude the concept of two distinct patterns and features: early-stage (patch/thin plaque) and more advanced-stage (thick plaques/tumors). There appears to be a strong correlation between the clinical assessment of early-stage type lesions versus more advanced-stage lesions and treatment outcomes, similar to the stages of more prevalent types of mycosis fungoides. Treatment approaches may be different depending upon the distinct pattern of the disease.

Pediatric Mycosis Fungoides: Generally, MF is not seen often in the pediatric population. However, 4-5% of cases in the US are in children. Overall, hypopigmented MF is the most prevalent variant in children. Clinical presentation, prognosis, and response to treatment are poorly described because of the small number. Diagnosis is usually delayed due to its similarity with other common childhood hypopigmented diseases. There are no treatment guidelines explicitly made for this population. Prognosis is generally good, although there is a high relapse rate, which requires long-term follow-up. Hypopigmented MF is the most prevalent variant in children and adolescents. Phototherapy is the most used treatment, and most patients present with early-stage (IA and IB) disease.

Sezary Syndrome: The diagnosis of Sezary is often impaired by the distinct lack of unique diagnostic blood markers that clearly allow the identification of the malignant T-cell population in the blood. Several markers are known and characterized, such as CD7 and CD26 loss and the gain of PD-1 and CD158k. It is yet to be clarified which of these markers best describe the malignant population and how these markers correlate with T-cell receptor (TCR) clonality, the defining feature of the cancerous Sezary cells. The established

cell markers vary in specificity and sensitivity and can only be used in combination. This underlines the need for more work to be done to establish unique markers and standardized diagnostic panels.

Cutaneous B-Cell Lymphoma: This rare form of cutaneous lymphoma was first classified in 1986 and makes up 25% of primary cutaneous lymphomas. Most cases present with solitary or grouped lesions being typically treated successfully with local treatments to those lesions. Generally, this type of cutaneous lymphoma has a slow growth course. Further studies evaluating the impact of this type of lymphoma on quality of life may help guide treatment decisions and determine which patients benefit from which kind of treatment.

Rare Variants: Several presentations were shared discussing small studies related to rare variants of cutaneous lymphoma. Given these rarer subtypes have much smaller patient populations, it is difficult to gather data. However, there is considerable interest among the clinical community to share and understand how these rare subtypes present and respond to treatments. Many rare subtypes were discussed, including subcutaneous panniculitis-like T-cell (SPTCL), granulomatous slack skin, primary cutaneous gamma delta, and CD8+ mycosis fungoides with palmaris/plantar cutaneous T-cell lymphoma. More data sharing among the clinical and research community will help guide treatment pathways and inform new therapy development.

CD30+ Lymphoproliferative Diseases: Lymphomatoid papulosis (LyP) and primary cutaneous anaplastic large cell (pcALCL) are two ends of a spectrum of this type of cutaneous lymphoma. LyP has been shown to have a variety of different subtypes. Discussions focused on a proposal to redefine these into a more descriptive approach that can better guide treatments and distinctions between the subtypes.

Global Research Initiatives: Updates from the Cutaneous Lymphoma International Consortium (CLIC) PROspective Cutaneous Lymphoma International Prognostic Index study (PROCLIP) were shared. This study reports on first-line treatments used in advanced-stage MF with the objectives to determine differences in treatment approaches and describe response rates. The study included 362 advanced-stage MF patients from 41 centers in 16 different countries, capturing data from 2015 through 2018. The high-level outcomes showed that there were differences in treatment approaches according to stage of the disease. However, the majority of patients received similar treatments as first-line across all centers. However, the study also showed a wide range of treatment options used across the clinical centers. More work is required to determine which treatments to use at what point in time for which patient.

Quality of Life: An entire afternoon session was devoted to sharing data from several different studies related to patients' quality of life. The impact of all forms of cutaneous lymphoma on an individual's ability to manage their life well while living with cutaneous lymphoma is now being documented scientifically. This work will help incorporate the non-disease specific challenges that patients face every day. These studies demonstrated the physical, emotional, psychological, and day-to-day challenges people face globally. Overall, the time to diagnosis is long and frustrating. The general misdiagnosis of the disease, along with the path to getting an appropriate diagnosis is daunting and unsettling. Compared to other dermatological disorders, cutaneous lymphoma appears to have more of a negative impact on the overall quality of life. Quality of life scores go down as the disease stage, or aggressive nature of the disease, continues. Younger patients seem to have a more significant challenge. Financial burden plays a role as well. Generally, assessment of the quality of life issues are not captured well and are not explored consistently across clinical centers. Identifying the unique concerns of patients living with cutaneous lymphoma, including difficulties with sleep and self-image, is crucial in developing a comprehensive quality of life instrument that adequately captures the individual patient's experience. More work is required to understand this aspect of cutaneous lymphoma, including differences between gender, age, race/ethnicity, and country.

Following the 4th World Congress of Cutaneous Lymphomas, which took place in Barcelona in February of 2020, we followed up with two participating clinicians, Dr. Robert Knobler and Dr. Christiane Querfeld, to survey them about their take-aways from the Congress.

What was your biggest take-away from the Congress?

Dr. Knobler: Excellent worldwide communication among investigators (e.g., PROCLIP project) even before the COVID-19 pandemic!

Dr. Querfeld: New insights of the role of the surrounding tissue microenvironment in cutaneous T cell lymphoma. We are increasingly understanding how the cancerous T cells communicate with other cells in their vicinity to render them ineffective. So instead of killing the cancerous cells they support their growth. Within this context, the goal of lymphoma research has been to identify the role of specific tissue alterations at various stages of the CTCL.

continued on page 8

4TH WORLD CONGRESS...continued from pg 7

If you were to share that with one of your patients, what would you tell them that would directly impact them and their disease?

Dr. Knobler: New clinical trials that may be relevant for their disease.

Dr. Querfeld: Biologic behavior and the clinical variant of cutaneous T cell lymphoma may be most important. Good social support is equally important based on the research on quality of life that was presented.

What excited you the most about the Congress? Surprised you?

Dr. Querfeld: The role of the microenvironment in cutaneous lymphoma development is increasingly being acknowledged, together with its potential for therapeutic targets.

What do you think is one of the most important learnings presented at the Congress?

Dr. Querfeld: The PROCLIFI international collaboration

and useful model that helps to identify patients at risk of disease progression.

In your opinion, what is the most important or impactful research that needs to be done based upon what was shared during the Congress?

Dr. Knobler: Improve the inclusion of clinical trials at an international level.

Dr. Querfeld: We need to treat the cancerous cells, but also the surrounding environment that supports the growth of CTCL. Working together in international and national collaborations to fight this disease is important and also helps to develop new therapies much faster.

Answers provided by:

Dr. Robert Knobler
Medical University of Vienna

Christiane Querfeld, MD, PhD
Beckman Research Institute of the City of Hope

FLASH STUDY DEMONSTRATES INCREASED EFFICACY WITH CONTINUED TREATMENT IN PATIENTS WITH CUTANEOUS T-CELL LYMPHOMA

Soligenix, Inc. announced that continued treatment with SGX301 (synthetic hypericin) twice weekly for 12 weeks increased the positive response rate to 40% ($p < 0.0001$ compared to placebo and $p < 0.0001$ compared to 6-weeks treatment) in the open-label treatment cycle (referred to as Cycle 2) of its pivotal Phase 3 FLASH (Fluorescent Light Activated Synthetic Hypericin) study for the treatment of early-stage cutaneous T-cell lymphoma (CTCL). (see details here) These highly statistically significant results confirm the benefit of continued SGX301 treatment in CTCL patients.

Soligenix previously announced positive top-line results when the study achieved statistical significance ($p = 0.04$) in its primary endpoint over the first 6 week double-blind treatment cycle (referred to as Cycle 1) (available here). The study enrolled 169 patients randomized 2:1 to receive either SGX301 or placebo in Cycle 1. After the subsequent additional 6-week treatment in the open-label Cycle 2, the response rate in patients receiving a total of 12 weeks treatment increased two and a half-fold. Treatment responses for each cycle were assessed at Week 8 (after 6 weeks of treatment) and at Week 16 (after 12 weeks of treatment). A positive response was defined as an improvement of at least 50% in the Composite Assessment of Index Lesion Score (CAILS) for three index lesions evaluated in both Cycles

1 and 2. The data continues to indicate that SGX301 is safe and well tolerated.

“As anticipated, the data continues to become more compelling with extended SGX301 treatment,” stated Ellen Kim, MD, Director of the Dermatology Clinic, Perelman Center for Advanced Medicine and Lead Investigator of the FLASH study. “This treatment response is comparable to other, less safe, treatment alternatives, showing a statistically significant response at just 6 weeks, which continues to significantly increase with more treatment. The response rate at 12 weeks is similar to other therapies, some of which patients must take for more than a year. In addition to the efficacy demonstrated, SGX301 remains well tolerated with a unique mechanism of action that is not associated with DNA damage like other currently available therapies. I look forward to working with Soligenix to move this important new therapy forward with the US Food and Drug Administration (FDA) so that patients may access it as soon as possible.”

Soligenix would like to again extend their sincere appreciation to the patients, families, investigators, and advisors involved in the pivotal Phase 3 FLASH study and for those that recently participated in the SGX301 education podcast conducted by the CLF. 

Quality of Life...continued from pg 1

A study conducted by the University of Pittsburgh Medical Center looked at how caregivers play a critical role in any illness, though their personal reactions, willingness, and abilities differ. Often the health of a caregiver can change or suffer as a result of depression, anxiety, sleep problems, and/or social isolation. There is a gross lack of studies focusing on QoL in caring for patients with cutaneous lymphoma. It was hypothesized that a unique caregiver burden and quality of life for the caregivers of cutaneous lymphoma patients exists, and as such, there may be unidentified, and thus unmet, caregiver needs. (McCann, et al., 2017). This study sought to explore the unknown and unmet needs of caregivers; to identify caregiver burdens and QoL issues, to determine if the caregiving burden/QoL differed depending on the stage of the patient's skin burden as the caregiver perceived it to be, and among other things, to determine if caregiver needs were being met by the healthcare providers. This study concluded that data trends, rather than significance of data, that were identified to support the hypothesis. Moderate and severe disease assessment correlated with caregivers being more bothered by itching and scratching behaviors, and healthcare providers recognizing the burden and offering increased support. For caregivers rating their loved one's illness as moderate to severe, they reported their caregiver burden being more affected by skin symptoms versus other health problems.

The above information serves as a brief overview of some of the quality of life data collected from various surveys that have been conducted. More studies are on the horizon to dive deeper into this important topic and to alleviate some of the burdens associated with living with cancer or caring for someone who

has it. It's important to remember that emotional issues can impact a person's quality of life in a big way, just as physical issues can. Quality of Life is as important to a person's well-being as is treating physical symptoms. Never hesitate to discuss any concerns you may have regarding your own quality of life, that's what they are there for – to treat you as a whole person – your mind and your body.

Sue McCann, MSN, RN, DNC
University of Pittsburgh Medical Center

Marianne Tawa, RN, MSN, ANP
Center for Cutaneous Oncology
at Dana Farber Cancer Institute

McCann, S., Huwe, J., Lipner, C., Astley, E., Apfel, A., Fabio, A., & Akilov, O. (3 C.E.). (2017) Caregiver Burden and Quality of Life Factors Affecting Caregivers Caring for Patients with Cutaneous T-Cell Lymphoma.

Molloy, K., Jonak, C., Woei-A-Jin, F., Guenova, E., Busschots, A., Bervoets, A., Hauben, E., Knobler, R., Porkert, S., Fassnacht, C., Cowan, R., Papadavid, E., Beylot-Barry, M., Berti, E., Alberti Violetti, S., Estrach, T., Matin, R., Akilov, O., Vakeva, L., Prince, M., Bates, A., Bayne, M., Wachsmuch, R., Wehkamp, U., Marschalko, M., Servitje, O., Turner, D., Weatherhead, S., Wobser, M., Sanches, J., McKay, P., Klemke, D., Peng, C., Howles, A., Yoo, J., Evison, F. and Scarisbrick, J. (2020), Characteristics associated with significantly worse quality of life in mycosis fungoides/Sézary syndrome from the Prospective Cutaneous Lymphoma International Prognostic Index (PROCLIPI) study. Br J Dermatol, 182: 770-779. doi:10.1111/bjd.18089

From the CEO...continued from pg 3

As I've said many times, quoting one of our beloved clinicians, Dr. John Zic, "24 hours a day, somewhere in the world, there is a researcher working on cutaneous lymphoma." There is hope. There is a path forward. There is a better tomorrow.

Enjoy the content in this edition. Take care of yourself and your loved ones. We are holding you close in our hearts and looking forward to the day when we can gather together again in person.

In the meantime, make sure to check out our brand-new **Cutaneous Lymphoma Community Connections**. We are thrilled to be able to bring this peer-to-peer networking platform to you. Hope to see you in the "Community!"

Sending you all virtual hugs,

Susan



Don't miss out, make sure to subscribe to the Cutaneous Lymphoma Foundation's YouTube channel (CutaneousLymphomaFnd) and follow us on Facebook and LinkedIn.

For a list of our current virtual programs, please visit our website:

<https://www.clfoundation.org/upcoming-events>

CUTANEOUS LYMPHOMA FOUNDATION

Get Ready To  **Get Your Move On!**
Let's Move Together to Beat Cutaneous Lymphoma

WHO: Anyone can participate!

WHAT: Compete to raise money and time spent being active. Will you be our leading fundraiser, the leading participant logging the most hours of movement, or both?

WHEN: Registration Opens: August 15, 2020
Event Date(s): September 12 - September 19
Award Event: September 23

WHERE: Wherever you are – this is a virtual fundraising event!

HOW: **STEP 1:** Register to participate!

STEP 2: Ask your network to sponsor you or join your team, and together you'll raise money while tracking your time spent moving! Moving is moving – embrace your passion...walking, biking, swimming, golfing, hiking, yoga, or any other activity you enjoy doing!

STEP 3: Time to Get Your Move On!
Keep track of your time and activity on an activity tracker or on a paper log.

STEP 4: Submit your results to see who wins!

WHY: Make a difference in your life, and the life of others affected by cutaneous lymphomas!

Let's move together to beat cutaneous lymphoma!

Do not want to participate? Support through a donation is always welcomed and appreciated.

**In Memory of
Dr. Thomas F.
Anderson**



The Cutaneous Lymphoma Foundation is deeply saddened to say goodbye to Dr. Thomas Anderson of the University of Michigan. Dr. Anderson joined the University of Michigan Department of Dermatology faculty as an instructor in 1978, was promoted to assistant professor in 1979, and to associate professor in 1983. He retired from the University of Michigan in 2017. His expertise in the area of photo medicine enriched education and clinical research missions and patient care programs in the areas of psoriatic skin disease and cutaneous T-cell lymphoma. As a clinical educator and attending faculty physician, he provided instruction to future doctors in the lecture hall, conference and patient care settings, including countless medical students and more than 250 dermatology residents at the University of Michigan.

Frequently Asked Questions

Answers provided by:

Lauren Pinter-Brown, MD

Chao Family Comprehensive Cancer Center

Jasmine Zain, MD

City of Hope National Medical Center

Welcome to our new Frequently Asked Questions section, formerly our Skincare Corner. Check each issue for questions that come up repeatedly in our programs and that may have been discussed within our online Community.

We would like to give a special thanks to Meredith Haab, who has facilitated the Q&A for our Skincare Corner for the past several years.

What is a punch biopsy and when is it appropriate to get one done?

Dr. Lauren Pinter-Brown: A punch biopsy is a form of skin biopsy – there are basically two different common forms, one is a punch. The person doing the biopsy uses an instrument that looks like a miniature cookie cutter to cut out a circular piece of skin that is then sent to the pathologist to look at it. The other type of skin biopsy is called a shave biopsy. Basically the person doing that shaves a little bit of skin off, and so it looks like a pencil shaving. And so we get any of those skin biopsies, either kind, when we're having a question about what is appearing on someone's skin and we want to understand it better.

Dr. Jasmine Zain: I sometimes try to get the punch biopsy if I'm trying to look at the depth of a tumor and if they're concerned about folliculotropic type of MF where it can involve hair follicles and deeper tissues. For the most part, either one of those is fine – it's important to get the biopsy to confirm disease progression and transformation and what's going on inside the tumor.

What's the best way to ensure that a skin biopsy will generate accurate results? I heard that if you're being treated with topical steroids that it's harder to get an accurate read of the disease in the skin.

Dr. Lauren Pinter-Brown: Yes, that's true. If someone is either taking steroids orally or is putting them on their skin, it makes it harder for the pathologist to read the biopsy because steroids kill lymphocytes and lymphocytes are the

cells that they're looking for to diagnose a lymphoma. So, I would tell people that it would be best if they would refrain from all steroid use for a period of about four to six weeks before the biopsy is taken, and then we try to biopsy the lesion that's maybe the thickest or the most angry looking so that the pathologist can get the best tissue and try and make a diagnosis.

Dr. Jasmine Zain: I do realize that sometimes a patient's symptoms are so severe that they can get really itchy, it's uncomfortable for them to be off of steroids for very long, but again, every attempt should be made to try to minimize their use before the biopsy. Otherwise the biopsy is not as useful or as informative. That's something to discuss with your doctor and make sure that you're off steroids before the biopsy is done.

If you have mycosis fungoides, even if you're early stage, are you at higher risk to get COVID-19?

Dr. Lauren Pinter-Brown: I think the issue is not the risk of getting it, but the risk of having a more severe case. And I think for safety, I would assume that anyone who has had a diagnosis of lymphoma is at higher risk for having more serious disease and they should be particularly careful. And if that's overly careful then that's fine with me. Because we're trying to make sure that people are safe.

Questions and responses taken from our Answers from the Experts LIVE video recording from April of 2020. For the full-length video, please visit: <https://www.youtube.com/watch?v=yTTqBjYL3QU&feature=youtu.be>





CUTANEOUS LYMPHOMA FOUNDATION
PO BOX 374
BIRMINGHAM, MI 48012

TIME SENSITIVE MATERIALS ENCLOSED



CUTANEOUS
LYMPHOMA
*Community
Connections*

The power of the online
community, working
together to create
a movement that
revolutionizes the way
people live with
cutaneous lymphoma.

CONNECTIONS is a next-generation portal that combines the real-time collaboration of a message board with the ability to share materials, resources, and information on a variety of devices.

CONNECTIONS is a platform that provides the Cutaneous Lymphoma Foundation staff a direct, personal way to serve our community more effectively and communicate updates, opportunities, and events more efficiently, while enabling enhanced personal interaction and collaboration among members of the community.

CONNECTIONS provides a robust platform to build specific groups around topics or disease types, allowing us to provide better service by enabling people to find information and assist each other online.

CONNECTIONS provides an empowered patient organization, leveraging all touch points with the people it serves, and is able to share information seamlessly. Using this type of technology allows us to connect people and create programs that deliver more impact.