Transforming Blood Cancer Care: The Role of Clinical Trials and CAR T-Cell Therapy

This activity is supported by independent educational grants from
Stemline Therapeutics, Inc., Kite Pharma, Inc., and Novartis Pharmaceuticals Corporation

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Welcome and Overview

Lauren Berger, MPH
Senior Director, Professional Education and Engagement
The Leukemia & Lymphoma Society

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The Leukemia & Lymphoma Society

- World's largest voluntary health agency dedicated to blood cancers
- Mission is to cure leukemia, lymphoma, Hodgkin's disease and myeloma, and improve the quality of life of patients and their families
- Invested over $1 billion in research
- Committed to educating those affected by blood cancers about the potential life-saving treatment option of clinical trials
- Committed to providing free information and support services

Website – www.LLS.org 1.800.955.4572

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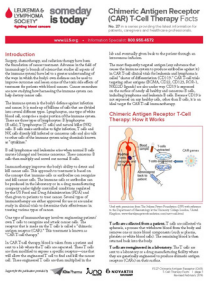
Individual Support Resources

- Printed materials – www.LLS.org/booklets
- Questions for patients to ask the healthcare team – www.LLS.org/whattoask
- Professional education webinars & videos – www.LLS.org/professionaled



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Individual Support Resources

- Patient education webinars & videos – www.LLS.org/programs / www.LLS.org/educationvideos
- Financial Support for Patients – www.LLS.org/finances
- LLS online social network for HCPs and patients to seek answers and share information – https://CommunityView.LLS.org

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Individual Support Resources

- Information Resource Center – call 1.800.955.4572
  email – infocenter@LLS.org
  - Clinical Trial Navigation Services
  - Growing awareness of LLS's significant service offerings in this area

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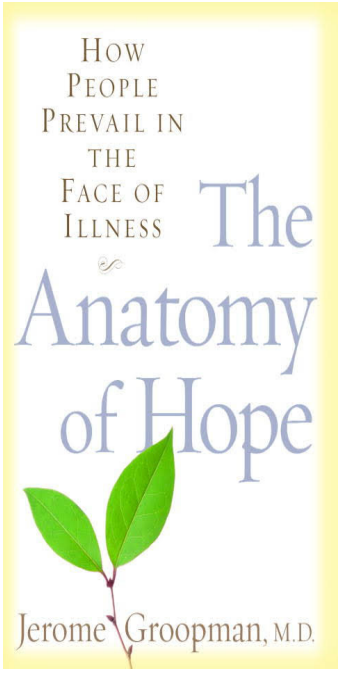
LEUKEMIA & LYMPHOMA SOCIETY® fighting blood cancers
someday is today®

Supporting Patients Through Education and Personalized Clinical Trial Searches

Margaret McCormick, RN, BSN, MA, MBA
Lead, Clinical Trial Support Services
The Leukemia & Lymphoma Society

"Each disease is uncertain in its outcome, and within that uncertainty, we find real hope, because a tumor has not always read the textbook, and a treatment can have an unexpectedly dramatic impact."

Jerome Groopman, MD



Treatment

1994 DLBCL of R Breast	CHOP and Radiation
2009 DLBCL of R Eye	Eye enucleation, Hyper CVAD, Rituxan, CNS prophylaxis w intrathecal ARA-C and Methotrexate
2014 Triple Neg Breast Cancer, R Breast	Bilateral Mastectomy, Carboplatin, Taxol
Jan 2015 DLBCL R pelvis	Beam, Rituxan

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Treatment (cont.)

- March 2015 contacted LLS to sort through autologous vs allogeneic transplant

May 2015	Autologous transplant
Jan 2016 Relapsed DLBCL R pelvis	Rituxan and Decadron

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Jamie

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Impending Crisis in Cancer Clinical Trials

- 40% of NCI-sponsored trials close without meeting accrual goals
- One-third of Phase III trials close because of poor accrual
- Failure to accrue prevents access to potentially life-saving treatments
- Implications for patients not offered potentially life-extending treatments

1. Kehl KL, et. al. *J Natl Cancr Inst*. 2014;106(10):1-2.

12

Question

Approximately what percent of patients with cancer participate in a clinical trial?

a. 3-5%
b. 8-10%
c. 20%
d. 30%

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Answer

Approximately what percent of patients with cancer participate in a clinical trial?

a. 3-5%

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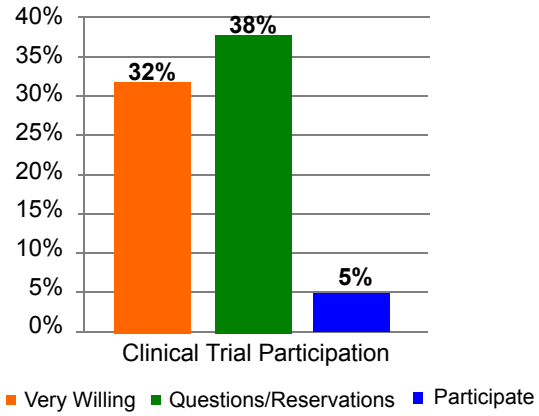
Most Interested; Few Enroll



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1. Comis RL, et al. *J Clin Oncol.* 2003;21(5):830-835.

Patient Barriers to Participation

- Frequently cited concerns
  - Side effects
  - Randomization
  - Financial concerns
  - Feeling overwhelmed
  - Increased time required
  - Geographical concerns

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Most Not Told of Possibility of a Trial

- 44% of eligible patients were not told of trials by treating physician[1]
- Only 20% potentially eligible for Phase II/III trials were offered enrollment, yet most who were offered enrollment participated[2]

1. Weckstein DJ, et. al. *J Oncol Pract. 2011;7(5):330-333.* **2.** Albrecht TL, et al. *J Clin Oncol.* 2008;26(16):2666-2673.

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Physician Barriers

- Poor impression of the trial's scientific merit
- Time and economic constraints, such as low reimbursement from the study sponsor
- Concern that the patient would not return to their practice if the study were discussed
- Perception that the patient may not understand the concept of a clinical trial

1. Manne S, et al. *Eur J Cancer Care (Engl).* 2015;24(1):28-38.

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LLS: Personalized Search Services

Arrival
Listen, evaluate needs, educate, support, refer

↓

Intake
Goals, physical status, diagnosis details, support system, travel, insurance/financial

↓

Comprehensive Search
Utilize intake information to narrow trial options

↓

Communicate/Connect
Physician-site, patient-site, LLS-site

↓

Enrollment
Trial enrollment OR continue to research and support

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Transforming Blood Cancer Care:
The Role of Clinical Trials and CAR T-Cell Therapy

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The Role of Clinical Trials in Treating Patients With Acute Myeloid Leukemia (AML): A Case Study

Monica Kwari, RN, BSN, CCRP
Research Nurse Supervisor
Department of Leukemia
MD Anderson Cancer Center

Slides courtesy of Margaret Green, RN, OCN®

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Question

What percentage of your patients are being treated for blood cancer?

a. 0-25%
b. 26-50%
c. 51-75%
d. 76-100%

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Answer

What percentage of your patients are being treated for blood cancer?

d. 76-100%

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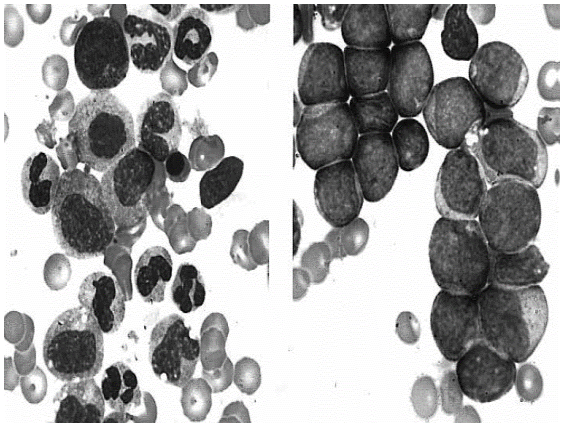
Overview of AML

AML is a heterogeneous hematologic malignancy of the myeloid precursor cell line characterized by the clonal expression of abnormal cells which accumulate in the bone marrow, peripheral blood and/or other tissues and interfere with the production of normal blood cells



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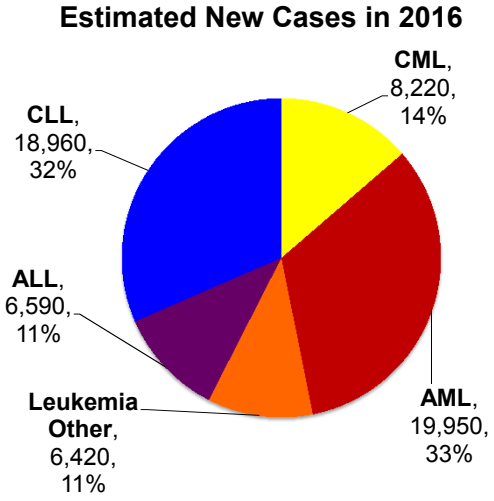
1. Acute Myeloid Leukemia Booklet. *The Leukemia & Lymphoma Society*. Revised 2015.

Overview of AML (cont.)

- Epidemiology in 2016:
  - ~19,950 people will be diagnosed in the US
  - ~10,430 will die from the disease
  - 26.6% surviving 5 years
- ***Profound unmet medical need despite various efforts in the past decades***



24

1. *SEER Stat Fact Sheet*: Acute Myeloid Leukemia (AML). **2.** *Cancer Facts and Figures, 2016*. American Cancer Society; 2016.

Overview of AML (cont.)

- Classification:
  - Immunophenotyping
  - Cytogenetics
  - Now gene sequencing can enhance risk stratification, prognosis, and allow more precise therapeutic interventions

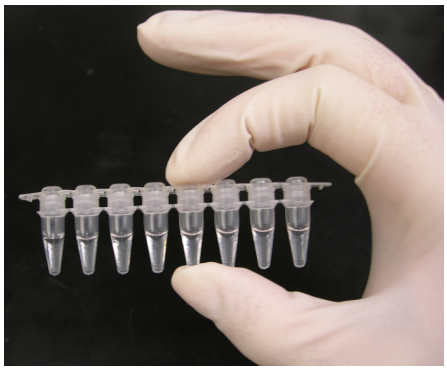


Photo courtesy of Madeleine Price Ball.

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FAB Classification

- M0 – AML minimally differentiated
- M1 – AML with minimal maturation
- M2 – AML with maturation
- M3 – Acute promyelocytic leukemia
- M4 – Acute myelomonocytic leukemia
- M4 eos – Acute myelomonocytic leukemia with eosinophilia
- M5 – Acute monocytic leukemia
- M6 – Acute erythroid leukemia
- M7 – Acute megakaryoblastic leukemia
- BPDCN Blastic Plasmacytoid Dendritic Cell Neoplasm

1. Acute Myeloid Leukemia Booklet. *The Leukemia & Lymphoma Society*. Revised 2015.

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AML Subtypes Based on the WHO Classification

- AML with recurrent genetic abnormalities
  - AML with translocation between chromosomes 8 and 21
  - AML with translocation or inversion in chromosome 16
  - AML with translocation between chromosomes 9 and 11
  - APL (M3) with translocation between chromosomes 15 and 17
  - AML with translocation between chromosomes 6 and 9
  - AML with translocation or inversion in chromosome 3
- AML (megakaryoblastic) with a translocation between chromosomes 1 and 22

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1. The Leukemia & Lymphoma Society. *Acute Myeloid Leukemia Booklet*. Revised 2015.

AML Subtypes Based on the WHO Classification (cont.)

- AML with myelodysplasia-related changes
- AML related to previous chemotherapy or radiation
  - Alkylating agent-related AML
  - Topoisomerase II inhibitor-related AML
  - Acute basophilic leukemia
  - Acute panmyelosis with fibrosis

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AML Subtypes Based on the WHO Classification (cont.)

- Myeloid sarcoma (also known as granulocytic sarcoma, chloroma or extramedullary myeloblastoma)
- Undifferentiated and biphenotypic acute leukemias (also known as mixed phenotype acute leukemias)
  - Acute basophilic leukemia
  - Acute panmyelosis with fibrosis

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Molecular Information: Next-Generation Sequencing

- NRAS, KRAS, FLT3
- IDH1/2, JAK2, K KIT
- NPM1, MLL-PTD, TET2, RUNX1
- DNMT3A 2, TET2, ASX L1
- TP53IT, EZH 2

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Isocitrate Dehydrogenase (IDH) Mutations as a Target in AML

- *IDH* is an enzyme of the citric acid cycle
- Mutant *IDH2* produces 2-hydroxyglutarate (2-HG), which alters DNA methylation
- Mutations in *IDH2* have been found in approximately 15% of AML patients

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Current Treatment

- Standard of Care Chemotherapy
  - Induction: Cytarabine and Daunorubicin
  - Consolidation: High-dose cytarabine 1 or 2 cycles
- Hypomethylating Agents
  - Decitabine: 5 or 10 days
- Stem Cell Transplant: dependent on risk stratification
  - Autologous, Allogeneic, Haplo, Cord, MUDt
- Clinical Trials
- CAR T for AML
- Compassionate use or expanded access to drugs under investigation but not yet approved by the FDA

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Therapies Under Investigation

- Flt3 inhibitors
- IDH1 & IDH2 inhibitors
- Antibodies with new targets
  - CD25, CD47, CD125
- Development of second- and third-generation drugs
- Vaccines intended to harness the immune system to recognize and attack leukemia cells

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Question

How likely are you to bring up the topic of clinical trials for a newly diagnosed patient?

a. Very often include clinical trials in discussion with newly diagnosed patients
b. Likely will
c. Not very likely
d. I don't work directly with patients

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Answer

How likely are you to bring up the topic of clinical trials for a newly diagnosed patient?

c. Not very likely

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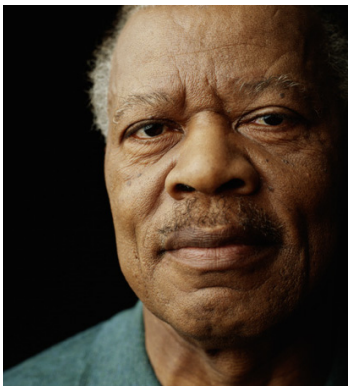
Case Study

- A 68-year-old male with essential thrombocytosis diagnosed in 1999
- Treated with hydrea transformed to AML (JAK2 mutated) in 2015
  - Cytogenetics: Complex with multiple abnormalities
  - Genetic sequencing revealed an IDH2 mutation



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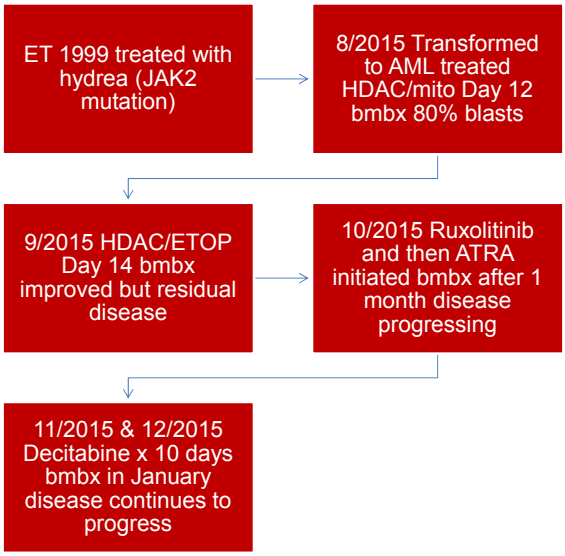
Treatment



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Complications During Treatment

- Pulmonary Hypertension
  - 2nd to h/o multiple PEs & DVTs
- Ischemic Stroke
  - Right hand dysfunction requiring rehabilitation
  - PS improved, pt transitioned to outpatient PT
- Infection with Neutropenia
  - ESBL *E. Coli* carbapenem-sensitive

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Clinical Trial: IDH2 Inhibitor Study

- Mutational analysis revealed IDH2 mutation
- Patient consented, screened and deemed eligible
- Therapy with investigational drug initiated 1/12/2016
- Patient improved clinically
- Bmbx 3/2016 revealed only 7% blasts and normal cytogenetics

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Communication With Patient

Provide info about clinical trials

- Consent
- Screening and eligibility
- Randomization
- Investigational drug
- Side effects and management
- Schedule and follow up

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Communication With Patient (cont.)

Possible side effects

- Nausea/Vomiting
- Diarrhea/Constipation
- Feeling tired and weak
- Fever
- Dyspnea
- Cough
- Decrease in WBC/RBCs

Management

- Antiemetics
- Supportive management
- QOL surveys to monitor
- Antipyretics
- Monitor for infection with supportive management, prophylaxis
- Transfuse as needed

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Psychosocial/Support Issues

- Emotional support
- Honesty without removing hope
- Insurance
- Compassionate-use drugs when patients are not eligible or no clinical trial is open

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Question

If your patient needs a drug that is only being offered in a clinical trial and that trial is closed, what would you do?

a. Tell the patient the drug is not available
b. Seek out compassionate use
c. Refer the patient to a center that runs clinical trials
d. Call the LLS Information Resource Center
e. I don't work directly with patients

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Answer

If your patient needs a drug that is only being offered in a clinical trial and that trial is closed, what would you do?

b. Seek out compassionate use
d. Call the LLS Information Resource Center

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The Evolving Role of Treating Patients With CAR T-Cell Therapy: A Case on Diffuse Large B-Cell Lymphoma (DLBCL)

Brenna Hansen, BSN, RN, OCN®
Research Nurse Specialist
Center for Cancer Research

NIH NATIONAL CANCER INSTITUTE

April 29, 2016

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Diffuse Large B-Cell Lymphoma

NIH NATIONAL CANCER INSTITUTE

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Diffuse Large B-Cell Lymphoma (DLBCL)

- Cancer of mature B-cells
- Most common subtype of non-Hodgkin lymphoma with around 25% of non-Hodgkin lymphoma cases[1]
- DLBCL category is heterogeneous in morphology, genetics, and biologic behavior with 10 subtypes[2]
- Approximately 60% of patients have advanced–stage disease at diagnosis while 40% will have more localized disease[3]

1. Swerdlow SH, et al. *IARC Press, Lyon*. 2008. **2.** Zelenetz AD, et al. *J Natl Compr Canc Netw*. 2016;14(2):196-231. **3.** Armitage JO, et al. *J Clin Oncol*. 1998;16(8):2780-2795.

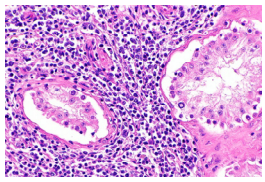
Diffuse Large B-Cell Lymphoma (DLBCL) (cont.)

- 5-year overall survival rate for Non-bulky Disease 95% (Mass<7.5 cm)[1]
- 5-year overall survival rate for Bulky Disease 60% (Mass>7.5 cm)[1]
- Of patients who relapse after first-line therapy, less than 10% experience disease-free survival with second-line treatment regimens[2]

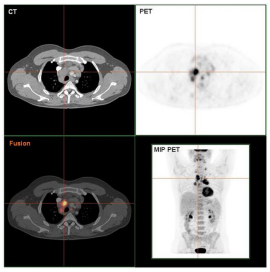
1. Miller TP. *J Clin Oncol*. 2004;22(15):2982-2984. **2.** Gisselbrecht C, et al. *J Clin Oncol*. 2010;28(27):4184-4190.

Diagnosing DLBCL

- Presenting signs and symptoms can include swollen glands, night sweats, weight loss, abdominal pain
- DLBCL presents as a symptomatic rapidly growing mass, most usually in the neck or abdomen but can present anywhere in the body
- Diagnosed through pathologic evaluation of the tumor
- Excisional tissue biopsy of the tumor, typically a lymph node but can be other tissue
- PET-CT scans and diagnostic CT scans



Nephron, https://commons.wikimedia.org



Hg6996, https://commons.wikimedia.org

DLBCL Treatments

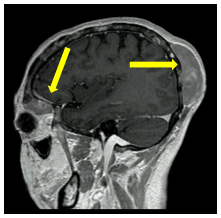
- First-line therapy:
  - R-CHOP (systemic chemotherapy cyclophosphamide-doxorubicin-vincristine-prednisone plus recombinant therapy anti-CD20 rituximab) with locoregional radiation therapy
  - Dose-dense R-CHOP14
  - Dose-adjusted EPOCH-R (etoposide-prednisone-vincristine-cyclophosphamide-doxorubicin-rituximab)
- Second-line therapy. Example GemOx
- Allogeneic stem cell transplants
- Clinical trials

1. Zelenetz AD, et al. *J Natl Compr Canc Netw*. 2016;14(2):196-231.

DLBCL Case Study

Sara is a 36-year-old women who goes to her doctor complaining of persistent night sweats and swollen lymph nodes in her neck. Upon exam, several unusual lumps are also noted on her head. She eventually has a PET-CT that shows high metabolic activity in her abdomen, neck and the palpable masses on her head. The largest head mass is biopsied and the pathology report confirms a diagnosis of double-hit diffuse large B-cell lymphoma. She immediately begins R-CHOP, but after 2 cycles she has had no sustainable response. She then begins second-line therapy. She progresses though RHyper-CVAD and starts DA-EPOCH-R.

She has an eight-year-old child and wants to see him grow up. Knowing from the start that double-hit DLCBL has a poor prognosis, she been researching clinical trials. She has read promising articles on the internet about CAR T-cell therapy.

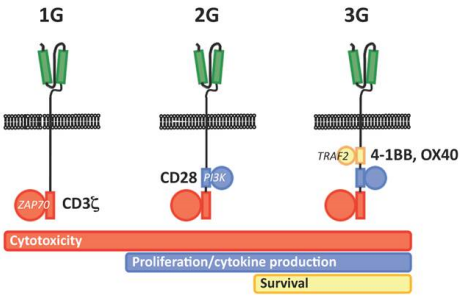


(Brudno et al. Journal of Clinical Oncology 2016)

CAR T-Cell Immunotherapy

What are CAR T Cells?

- Chimeric Antigen Receptor (CAR) T cells: T cells that are modified to express a CAR complex
- CAR: immunoreceptor engineered from parts from different sources
- The CAR is derived from a monoclonal antibody to be able to recognize a specific target
- Gene Therapy
- Precision Medicine
- Adoptive Cell Transfer



1.Casucci M, et al. *http://www.jcancer.org/v02p0378.htm.*
https://commons.wikimedia.org/wiki/File:Depiction_of_3_generations_of_CARs.jpg
2. https://commons.wikimedia.org/wiki/File:Depiction_of_3_generations_of_CARs.jpg

How are CAR T Cells Made?

Apheresis
T cells are isolated and collected from the patient's peripheral blood (leukapheresis)

↓

Activation of T cell
T cells are transformed into cytotoxic T cells

↓

Transfection
A gene is inserted using a virus that causes the CAR to be expressed by the T cell

↓

Cell Expansion
Cells are in culture, allowing them to expand and proliferate

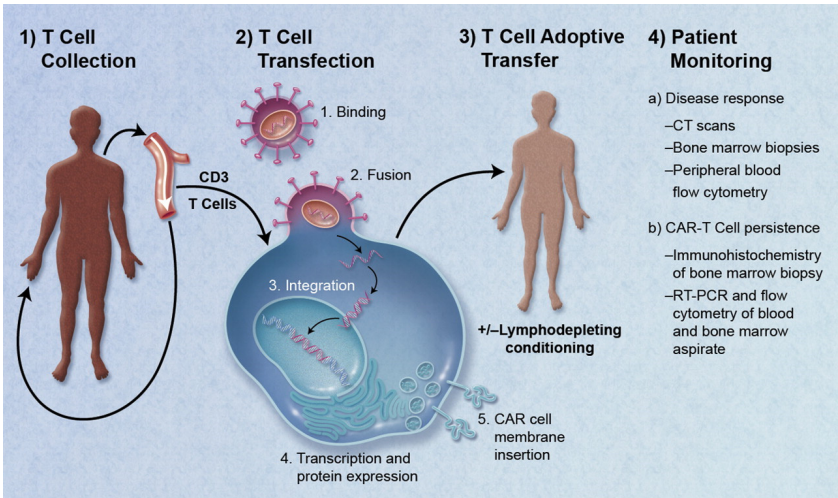
↓

Conservation
Cells are purified and cryopreserved (can be a fresh infusion)

↓

Administration
Cells are infused into the patient

How are CAR T Cells Made? (cont.)



1. Jacobson CA, et al. http://bloodjournal.hematologylibrary.org/content/118/18/4761.full .
2. https://commons.wikimedia.org/wiki/File:CAR-Engineered_T-Cell_Adoptive_Transfer.jpg

Types of CAR T Cells

- The different CAR T-cells target different specific surface proteins
- The targeted protein must be expressed by the cancer
- The targeted protein must NOT be also expressed somewhere in the body that could cause harm
- Targeted surface protein examples:

	Disease
CD19	Lymphoma and ALL
CD22	Non-Hodgkin lymphoma and ALL
CD30	Hodgkin lymphoma
BCMA	Multiple myeloma

National Cancer Institute (NCI), https://visualsonline.cancer.gov

CAR T-Cell Immunotherapy Treatment Schema

- Eligibility confirmation visit
- Apheresis
- Cell production and culture expansion
- Baseline evaluation
- Lymphodepleting chemotherapy conditioning
- Inpatient admission
- CAR T-cell infusion
- Inpatient monitoring for toxicities
- Local outpatient monitoring for toxicities
- Disease evaluation

CAR T-Cell Toxicities

- Cytokine release syndrome
  - Associated with CAR T-cell activity
  - Transient and variable (mild to severe)
    - Fever
    - Tachycardia
    - Hypotension
  - Early recognition of symptoms and careful monitoring essential
  - The risk period for the start of CRS is considered 4-7 days after cells are infused, but also can be earlier or later
  - Tocilizumab (targets IL-6R cytokine)
- Death
- Other toxicities

Are CAR T Cells a Good Option for a Patient?

- Must have the type of cancer the CAR T-cell targets
- The patient's cancer must express the targeted surface protein
- Able to tolerate apheresis (hbg, platelets)
- Needs to have a good performance status and adequate organ function
- The patient needs to have measurable disease
- Previous progression through standard therapy

Are CAR T Cells a Good Option for a Patient? (cont.)

- Have to be able to tolerate being off treatment for both the cell collection and the CAR T-cell infusion
- Uncertain response to CAR T-cell therapy
- Limited cell production slots
- Variable cell manufacturing time period
- Insurance may not cover CAR T-cell therapy

Supporting a Patient in a CAR Trial

Clinical:

- Maintain regular contact with home oncologist

Social Work:

- Locations limited (may require costly traveling and hotel stays for visits)
- May require extended time away from home, work, family for treatment
- May require a caregiver who will also need to take time from home, work, family
- Psychological support for family member and caregiver (low reserve)

Things to Consider

- CAR T cells are early experimental trials
- CAR T cells in the media
- Disease response is not guaranteed
- Enrolling and being treated on a CAR trial is a lengthy process
- All options and possible scenarios should be discussed with the patient
- Discuss the plan for if the patient is in remission after therapy
- The role of allogeneic stem cells transplants

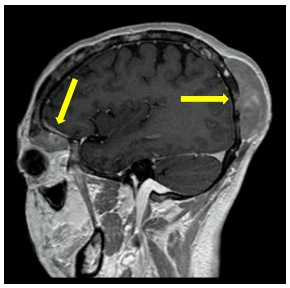
Revisiting the Case Study

Case Study

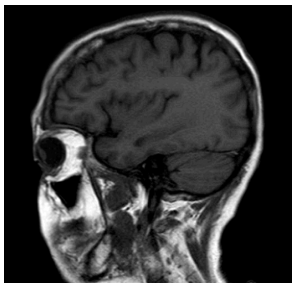
Sara sends her records and pathology to the clinical trial site and is deemed to be potentially eligible and her disease is confirmed to express CD19. She travels out of state for a week to be evaluated for the anti-CD19 CAR trial. She is confirmed to be eligible for the trial and has apheresis two weeks later on the date of the available cell production slot. Her T cells are shipped to the facility that manufactures the CAR T cells. The treatment date is not for another five weeks, so in the meantime her home oncologist gives her a short-course chemotherapy to make sure that she stays healthy enough for the treatment. The chemotherapy will be complete in time for the pre-treatment wash-out period. She knows that she will be out of state for the treatment for a month and so makes plans with her family that will allow her to have a caregiver without putting too much strain on them. She is eventually able to start treatment and receives the anti-CD19 CAR T cells. Four days post-infusion, she experiences fevers of 40.1 degrees Celsius, tremors, and requires pressor support for three days in the ICU. Two weeks after the infusion, all CRS toxicities have been resolved completely and the masses on her head are no longer palpable.

Case Study (cont.)

Before infusion



15 days after infusion



99 days after infusion

1. Brudno JN, et al. *J Clin Oncol*. 2016;34(10):1112-1121.

Acknowledgments:

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Caryn Steakley, RN, MSW
Elizabeth Ness, RN, MS
The Leukemia & Lymphoma Society

Patients who participate in clinical trials

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Transforming Blood Cancer Care:
The Role of Clinical Trials and CAR T-Cell Therapy

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Question & Answer

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Question

Have you found in clinical trials that they use the same apheresis line for the infusion itself or since these patients might require ICU care, are you using a different type of central line?

And are they mainly taken care of in an inpatient unit or ICU setting?

69

Answer

If a patient needs a central line for apheresis, they are going to need an apheresis line which is a larger line. You want to only use that for apheresis and use a central line such as a PICC line for the treatment itself.

70

Answer (cont.)

These patients can start their treatment on an inpatient unit with careful monitoring, with good communication with the ICU so that a transfer can run smoothly if needed. Not all CAR patients end up in the ICU.

71

Question

Can you speak more about the role of steroids in these patients because it seems a bit counterproductive to use those?

72

Answer

Steroids are avoided before apheresis and again before CAR T-cell therapy and after because they do effect the effectiveness of T cells. However, steroids can be used if the side effects of the CAR cells are severe enough that the patient's safety is a concern.

73

Answer (cont.)

You would not want to use them unless that was the case. Another treatment that can be used is tocilizumab to control side effects of the CAR T cells. However, again the theory is that these drugs can also effect the anti-tumor effect of the CAR T cells so you would not want to use them unless the patient's safety requires it.

74

Question

Is there one target that's shown to be more effective than other CAR Ts, like the CD19's better than the CD22 or have you seen better results with one target over another?

75

Answer

No, but many trials are still in early stages and there are other parts of the treatment that can differ. A patient should ask these questions when they are interested in the study because the research is being constantly updated.

76

Question

If they didn't require an apheresis line for collection, and they needed a line in the hospital, can the cells go through a PICC or a port or does it have to be a larger bore?

77

Answer

The cells themselves can go through any line that your hospital Standard Operating Procedure (SOP) determines is appropriate for cell infusion. Small gauge peripheral IVs would not be appropriate. A protocol may indicate a preference that should be followed.

78

Question

I'm just wondering what is the response rate for the CAR T cells of all the patients that you've seen?

79

Answer

This is constantly changing and updating especially since they are still early trials. I recommend looking at the most recent publications.

80

Question

When you're cultivating these T cells, there's a virus used to get the gene into the T cells. What viruses do you typically see used, and is there a decision process that determines which virus?

81

Answer

The decision of what virus to use is all scientifically chosen, and so it's going to be dependent on the protocol. One that I have seen recently is a type of lentivirus.

82

Question

What is the source of the gene that's inserted, and then how do you know if these target proteins are not expressed in other parts of the body besides the cancer?

83

Answer

The CAR complex is manufactured and can come from various sources. Early scientific studies are performed in early development of the CAR T cells, to make sure that the target protein is nowhere else in the human body that could harm any patient. New protein targets have to be tested very carefully.

84

Question

How long after the CAR T-cell infusion can some patients exhibit cytokine release syndrome (CRS) or symptoms?

85

Answer

This is going to vary, and it's going to continue to change. I have seen in some, CRS symptoms within two hours after infusion. The patient had the CAR T cells infused in the afternoon and was in the ICU before midnight. I have also seen patients who have had CAR T-cell side effects a couple of weeks after the infusion.

86

Answer (cont.)

As these cells are modified and improved, they can potentially become more potent and last longer in the body. This means that the general accepted four to ten-day range is going to change; and our practice and education will have to change around that to make sure that we stay updated.

87

Question

The process before apheresis, are they mobilized with high-dose filgrastim (Neupogen®)?

88

Answer

Filgrastim is used to mobilize stem cells into the peripheral blood stream. In this case they are just taking lymphocytes, so there are no drugs needed beforehand.

89

Answer (cont.)

You have to have baseline good condition of your T cells and be able to tolerate apheresis. The apheresis is a much shorter apheresis procedure than you would have for a stem cell transplant collection.

90

Question

You mentioned that chemo-conditioning was a lower dose. What are the drugs that you typically use for that?

91

Answer

At our site we use fludarabine and cyclophosphamide, but at lower doses since the chemotherapy is not used to fight cancer but lower the immune system to “make room” for the CAR T cells.

92

Answer (cont.)

Patients are more used to high-dose cyclophosphamide and the side effects that come with that, so the difference should be explained. At the lower doses, the most common subjective side effects are nausea and vomiting and in general, is well tolerated.

93

Question

Assuming that a patient meets all the criteria for support, obviously, you're doing this in a big university setting. I'm wondering about community practice and if you have any advice as to how to help encourage patients to maybe just broadly sign up for clinical trials as well as the CAR T.

94

Answer

You can give them the information, content, and clinical site. They'll usually give resources on information about different facilities, a copy of the consent for the patient to look at and review to see if they're interested. But if they're just not interested you can't make them interested.

95

Answer (cont.)

You can refer them to The Leukemia & Lymphoma Society the telephone number is (800) 955-4572. Many times you don't have a lot of time in the clinic to talk to them about clinical trials and where they might fit in their treatment paradigm.

96

Answer (cont.)

Many patients are told that they should go to hospice and that there's nothing left that is available for them, which the physician really means there's nothing approved that's available for them. And sometimes they miss explaining that a clinical trial is a great option.

97

Transforming Blood Cancer Care:
The Role of Clinical Trials and CAR T-Cell Therapy

LEUKEMIA & LYMPHOMA SOCIETY® fighting blood cancers

someday is today®

Closing Remarks

Lauren Berger, MPH
Senior Director, Professional Education and Engagement
The Leukemia & Lymphoma Society

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Margot

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To every patient who has or attempted to participate in a clinical trial…and to every nurse that has helped them…

Thank you

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