

Chronic Graft-versus-Host Disease Consortium

National Cancer Institute | Fred Hutchinson Cancer Research Center | Stanford University | Dana Farber Cancer Institute | University of Minnesota | Vanderbilt University | H. Lee Moffitt Cancer Center | Medical College of Wisconsin | Washington University | Memorial Sloan Kettering

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Introduction

In 2005, a group of doctors in collaboration with the National Institutes of Health (NIH) created a way to score graft-versus-host disease (GVHD) to measure how serious it is. The NIH scoring system could help doctors compare information from different GVHD studies and get information that is more useful for their research.

The next step was to collect data directly from patients to support the new scoring method. The study that you have participated in, "Improving Outcomes Assessment in Chronic GVHD," was developed to meet this goal. Thanks to the participation of many patients, this study has helped us learn what questions to ask and what data to use to focus chronic GVHD research on the areas that are most important to patients like you.

What we learn will be very useful in future clinical trials that study drugs to treat chronic GVHD. We believe that a good treatment is one that improves the quality of your life and helps you live free of your disease for a longer time. Having clear and consistent measurements in our research will help us know if a specific treatment helps patients meet the goals of living longer, healthier lives.

As you read this resource, you will notice that we mention a lot of data that was reported by patients. This is information that we collected from your study surveys. Thank you for taking the time to complete them!

The following is a summary of our research findings that have been published or presented at medical conferences.

Research Summaries

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1. Quality of life and chronic GVHD severity according to the NIH criteria

The goal of this project was to see how well the NIH severity scoring system matched with what patients reported about their quality of life.

The researchers found that it matched well, even when they took other factors, such as age, into account. They also looked at how chronic GVHD affected quality of life compared with other diseases.

Patients with moderate or severe chronic GVHD had quality of life similar to people with immune system disorders such as lupus or multiple sclerosis.

2. Chronic GVHD Severity and Sensitivity to Change in Patient-Reported Quality of Life

This study looked to see if there is a relationship between changes in chronic GVHD severity over time and changes in patients' quality of life.

Changes in chronic GVHD severity were measured using the NIH scale, doctor reports, and patient reports. Researchers used specific sections of the patient survey to measure quality of life.

Patient-reported quality of life did not match well with changes in the NIH score or doctors' ratings of their patients' chronic GVHD. However, patient-reported quality of life did match well with how patients rated their chronic GVHD.

This means that while the NIH score and doctors' reports may be useful for studying symptoms, they do not give a full picture of the effect of GVHD on patients' quality of life. The only way to know about a patient's quality of life is to ask him or her.

3. Calculated NIH Response Correlates with Changes in Patient-Reported Symptoms but Not with Quality of Life

In this study, researchers looked at how well changes in the NIH scores matched with changes in quality of life reported by patients.

GVHD symptoms at follow-up visits were compared with those at baseline visits to learn if patients' GVHD treatment had helped. Patients who showed a clinical response to treatment also said they had

improvement in their GVHD symptoms, but not in their quality of life.

This suggests that the NIH scoring system could be used in the future to collect information from patients about symptoms, but not about quality of life.

4. Personality Influences Quality of Life Assessments In Patients After Allogeneic Hematopoietic Stem Cell Transplantation – Results from a Joint Evaluation of the Prospective German Multi-Center Validation Trial and the Fred Hutchinson Cancer Research Center

Some patients helped with this research by completing a survey that asked about personality traits such as optimism and agreeableness. The researchers wanted to look at how these traits might affect the way you answer the questions on your chronic GVHD research survey.

They found that personality traits did have a large effect on the answers to questions about quality-of-life. Researchers now recommend considering this in clinical trials that use quality-of-life as a measure of how well a treatment works.

5. Chronic GVHD Global Severity According to NIH Consensus Criteria

This study compared different systems of the body to learn if some systems had more of an ability to make a patient's overall chronic GVHD worse.

They found that chronic GVHD in the skin, lungs, or eyes was most likely to make a patient's overall chronic GVHD worse. They also found that when patients' GVHD was scored as mild, moderate, or severe based on the NIH scoring system, the majority (59%) fell into the moderate category.

Researchers now think that the NIH scoring system may need to be adjusted to separate patients within the moderate category.

Researchers also learned that factors such as donor match, conditioning intensity, or having acute GVHD before, were not linked to the NIH severity scores.

6. Comparison of Proposed NIH Response Criteria with Doctor-Reported Changes in Organ-Specific and Overall Response

This study compared the NIH scoring system with the reports that doctors make about the health of their patients, both in general and about specific parts of the body, such as the mouth, eyes, or skin. The goal of the study was to learn if the NIH scoring system would score patient health changes in a way that was similar to, or different from what a doctor would report.

The study found that the two reporting methods were generally alike, but there were some differences. For instance, doctors often thought their patients were doing better than what the NIH score showed.

7. Plasma cytokine concentrations according to chronic GVHD subtype

Scientists continue to look for markers in the blood that can help them understand chronic GVHD and how to treat it.

Cytokines are an example of these markers. They are chemicals made by cells in the immune system to communicate with other cells. They are widely suspected of playing a role in chronic GVHD.

Some patients donated research blood samples as part of this study. This allowed researchers to look at the levels of cytokines in blood samples from patients with and without chronic GVHD. They also compared levels between patients with high levels of symptoms; high levels of symptoms but not mouth or GI symptoms; and low levels of symptoms.

They measured the amounts of 13 different cytokines, and found one that was significantly higher in patients with chronic GVHD. They did not find a major difference between cytokine levels in the subgroups of chronic GVHD.

8. Change in NIH Skin Score 0-3 Correlates with Doctor- and Patient-Reported Skin Changes and Overall Survival

This study looked at the relationship between the NIH skin scoring system and patient-reported skin

changes, doctor-reported skin changes, and survival.

Patients and doctors rated how much they thought skin symptoms had changed between study visits. The NIH scoring system matched well with these ratings. An NIH skin score that got worse over time was found to predict a lower chance of survival. This means that the NIH score could be used alone to measure skin GVHD in research. It also means that the patient- and doctor-reported measures may not be needed.

9. Measurement of Mouth Chronic Graft-versus-Host Disease

The goal of this research was to find the best way to measure chronic GVHD symptoms in the mouth. The study looked at how doctors and patients scored mouth symptoms over time. Doctors and patients gave similar answers about changes in mouth symptoms between study visits. The presence or absence of mouth symptoms was not linked to how patients rated their quality of life. The researchers also found that there were six questions on the patient and doctor surveys that were best at predicting and measuring mouth symptoms for people with chronic GVHD.

10. Evaluation of Scales Correlated with Doctor and Patient-Perceived Symptom Change in Ocular Graft-Versus-Host disease

Researchers reviewed doctor and patient reports on changes in eye symptoms to see how well they matched up with the NIH scoring system.

Matching between the NIH scores and the doctor and patient reports was very good. This means that the NIH eye score, which is only one question, is a good way to measure change in ocular GVHD symptoms.

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11. Recommended Measures for Joint Chronic GVHD

Changes in joint tightness reported by doctors and patients were compared with range-of-motion scores and NIH scores.

Limited range of motion was found to be linked to chronic GVHD that lasted longer, and chronic GVHD that included skin symptoms, but it was not linked to other data such as the 2-minute walk test and grip strength.

The best ways to measure important changes in GVHD joint symptoms were found to be the NIH joint score, the range-of-motion scale, and a two-question section of the patient survey.

with a new diagnosis of chronic GVHD. We believe this will complement the information we have from patients who have had chronic GVHD for a longer time.

Will you use the data from the walk test, breathing test, and grip strength test that I do at study visits?

These tests are called “functional measures” because they help us measure your physical condition at the time of your clinic visit.

We have used this information in some of our studies. For example, we found that some people with certain types of GVHD symptoms seem to perform less well on these tests, either because of the GVHD itself or because of the treatments used to treat the GVHD.

This study helped us understand that people with these symptoms may be weaker, and perhaps we should try different treatments than what we are currently using.

Frequently Asked Questions

What does the research mean for patients with GVHD and their doctors?

Some results show that sections of the patient and doctor surveys are not very useful in helping researchers study chronic GVHD. These sections either provide the same information as other, simpler sections, or they don’t match up well with what patients are actually experiencing. We will use this information to design future studies and to make the patient and doctor surveys shorter.

More studies will be done to help adjust the NIH scoring system so that it matches better with what doctors and patients report about chronic GVHD.

Showing how chronic GVHD affects quality of life helps provide evidence for more funding and support for studying the prevention and treatment of chronic GVHD.

How many patients are in this study?

There are about 580 participants enrolled at study centers across the United States.

How long will this study continue?

This was originally a 5-year study, but has proven to be so useful that we applied for a funding extension to continue the research. Our focus will shift to collecting more information from patients

What are some future research projects that will use this data?

We are continuing to analyze the information we have already collected and are looking at the lung, intestine and liver now. We plan to use the information we have learned to help develop other studies. Many of the newer studies will test new treatments for chronic GVHD that we hope will be more successful and have fewer side effects.

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