Effects of Oral Dietary Supplementation with a Refined Lacteal Complex (Cyto-Ess™) upon Natural Killer (NK) Cell Activity in a Healthy Human Population

Quantum Research, Inc., Scottsdale, Arizona, September 1, 2001

ABSTRACT

INTRODUCTION

A small clinical trial to measure changes in Natural Killer (NK) cell function over a 90-day period in a test group comprised of healthy participants. No additional nutritional supplement or health improvement programs were included. Participants were advised not to alter their normal lifestyle during the study period.

The dietary supplement Cyto-Ess™ is produced by patented processes and proprietary methods developed and researched since the 1950's. Small clinical studies have demonstrated the efficacy of such refined lacteal complexes (RLC) in supporting immune system function and increasing Natural Killer (NK) cell activity. A double blind study revealed the immune modulation effects within a 15-day period.

DESIGN AND PARTICIPANT COMPLIANCE

Twelve participants, seven women and five men, were included. Ages ranged from 24 to 63 years. Each participant provided a blood sample for a Natural Killer Cell Function Test. All participants reported compliance with study instructions and took one 100 mg capsule of RLC twice daily for approximately 90 days. They were reevaluated by a second Natural Killer Cell Function Test upon completion of the trial period.

FINDINGS

Pre-study average NK cell activity was 30 Lytic Units (LU) and post study average NK cell activity was 101 LU for an average increase of 207% for the study group over a ninety-day period.

DISCUSSION

The study suggests a strong relationship between the daily ingestion of RLC and an increase in NK cell activity with no other additional nutritional supplementation, medication or lifestyle changes.

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INTRODUCTION

Refined Lacteal Complex (RLC), produced by patented processes and proprietary methods developed and researched since the 1950's, has been used for decades to provide immune system support. Several small clinical trials have demonstrated its efficacy for supporting immune system function and increasing Natural Killer (NK) cell function. A double blind trial has revealed the immune modulation effects of RLC within a 15-day period.

Sustaining healthy immune function has become a priority for those seeking good health. There is ever-increasing evidence of the immune suppressive consequences of poor nutrition and stress.

Re-establishing immune integrity through traditional nutrition shows very little promise. Traditional nutrition relies upon biochemical activity as a method of supporting the function of the immune system. This may not provide the components necessary to support immune communication pathways.

Communication in the immune system is accomplished through the cytokine mechanism. These messenger molecules must be activated to energize the communication capability that is necessary for immune system reliability.

An indicator that can be used to determine the status of the immune system is Natural Killer (NK) cell activity. Low Natural Killer cell activity is present in most illness and can be an indicator of developing disease or declining health. NK cells have been of interest to medical research since the early 1970's. Their role in immune health has been well established and they play an important role in immune function. NK cell activity can be evaluated with blood testing.

Activated NK cells produce a variety of cytokines, including interferons, interleukins, TNF, hematopoietic cell growth factors and other growth factors. There is substantial evidence that indicates the involvement of NK cells in the interactions of the immune system with the neuroendocrine axis. They also appear to be responsible for activities at the interface between the immune system and the reproductive and neurological systems.

NK cells are not restricted to immune surveillance. They are involved in a variety of essential biological processes ranging from reproduction to the management of daily stress.

There are a number of natural and synthetic substances that will temporarily stimulate NK cell activity. However, immune system response appears to be more enveloping and effective when achieved through the modulation process rather than stimulation or depression.

NK stimulation versus immune modulation with a resulting increase in NK activity has three major distinctions:

1. Stimulation will cause and initial rise in NK activity but after a short period of time the stimulation will diminish and the NK activity will return to baseline or below.
2. Stimulation has a limited effect on the immune system and does not affect the immune system as a whole.
3. Stimulation has limited effects on overall health.

Conversely, immune modulation will harness the body's ability to regulate and will encourage an all encompassing immune response not limited to one specific area. Regulation, upward or downward, in accordance with the needs of the body will be achieved.

RLC has a long history of empirical and antidotal evidence, as well as clinical trials on humans that have demonstrated its effectiveness as an immune modulator. Although the pathways of initiation by RLC are still being studied there appears to be an activation effect on B cells, T cells, macrophages, interleukins, interferons, TNF and other cytokines.

The cytokine launch initiated in immune modulation may produce a "spreading effect" that causes an increase in Natural Cell activity. This study examines the Natural Killer activity changes after the commencement of daily usage of RLC for the express purpose of determining its effect, acting as an immune modulator, on NK cell function.

ELIGIBILITY CRITERIA

The following eligibility criteria were applied to human subjects self-evaluated as healthy. They were required to be between the ages of 21 and 65 years, not suffering from severe or degenerative diseases, not currently experiencing any high stress circumstances, not taking any pharmaceutical medications for severe, chronic or degenerative diseases and not pregnant. They were advised not to alter their eating habits or lifestyle. Dietary supplements were acceptable if they were currently taking any, as well as the use of any medications or health care treatments that were deemed necessary during the course of the study.

STUDY DESIGN

Twelve participants were included in the study. The group was comprised of seven women and five men ranging in age from 24 years to 63 years. Each participant provided a blood sample for an NK cell Function Test and received a two week supply of 100mg capsules of RLC with a compliance form to record date and time of consumption.

RLC was taken twice daily; one in the AM and one in the PM. Every two weeks each participant returned to the research site to submit the compliance form, participated in a short interview and received another two weeks supply of the product.

After approximately 90 days of taking RLC the NK Cell Function Test was completed for each participant. Each participant received a six months supply of RLC for agreeing to participate, comply and complete the study.

Materials

Refined lacteal complex. It was utilized in dried powder form, encapsulated and bottled for the study.

Natural Killer Cell Function Test

Natural Killer (NK) cell activity and measurement of NK cell numbers can be evaluated by flow cytometry. Until recently, NK cell activity was measured by Cr-labeled leukemia cell line, K562, as target cells and peripheral blood mononuclear cells as effector cells.

However, developments in flow cytometry technology can now use K562 cells as the target cells that are labeled with fluorescent dye instead of radioactive chromium. The advantages of this method are increases in specificity, sensitivity and the absence of radioactivity in the assay. The results of NK assays are expressed as Lytic Units (LU) and the normal range is between 20 and 250 LU.

STUDY FINDINGS

Natural Killer Cell Activity

Pre-study average NK cell activity was 30 LU and post study average NK cell activity was 101 LU for an average increase of 207% for the study group over a ninety-day period. Two of the twelve participants had a decline in NK cell activity rather than an increase of NK cell activity. One had a 56% decrease while the other had a 9% decrease. Ten of the twelve participants had an increase in NK cell activity with the least increase at 67% and the greatest increase at 570 %. The five male participants had an average increase of 184% and the seven female participants had an average increase of 231%.

DISCUSSION

There has been a great deal of clinical, anecdotal and empirical evidence accumulated that demonstrates the benefits of RLC for immune system support. This study focused upon the change in NK cell activity during the supplementation of RLC in a healthy human population.

The benefits of RLC on NK cell activity have been documented in several studies where it was included in a holistic treatment regimen. The investigators in those studies concluded that the modulation effect along with a dramatic increase in NK cell activity could have only been the result of the addition of RLC. This was indicated as the same treatment regimen had not produced similar laboratory results (blood test monitored immunological responses) in the past. Also, the fact that patient outcomes in those studies were far superior to same treatment regimens without RLC further reinforces the correlation.

These studies help confirm years of clinical use in a medical practice where RLC demonstrated exceptional results in immune compromised patients. The result measured in this study was an increase in NK cell activity for 10 of the 12 participants for an average increase in NK activity of 207% in the ninety-day period.

The participant who had the highest pre-study NK cell activity also had the greatest post-study percentage increase with final NK cell activity increased by 570%.

The participant with the lowest pre-study NK activity had the least percentage of increase excluding two participants who experienced a decrease. These indicators appear to support clinical observations that some people have a more responsive immune system than others.

The two participants who had a decrease in NK activity had the 2nd and 3rd highest at the beginning of the study. The factors that contributed to the decreases were not identified, but post study interviews with the two men (both are business owners), revealed that in the week preceding their final blood test they both had very stressful events pertaining to their respective businesses. These events were reported as being well beyond normal business pressures and occupied most of their emotional and physical attention during that time. A possible correlation could be suggested.

The participant who had the 570% increase had just returned from a two week island vacation a few days before the final NK cell evaluation. This appears to be continuing confirmation of the dramatic effect that stress, or lack of stress, has on the immune system.

The findings of this study suggest a relationship between the daily ingestion of RCL and an increase in NK cell activity without the support of addition nutrition supplementation, medication or lifestyle alterations. As Natural Killer cell activity is associated with immune system health, RLC appears to provide support to the immune system in sustaining immune function.

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