

The Cellular Health Solution to Irregular Heartbeat:

*Results of a Randomized,
Double-Blind
Placebo-Controlled Study*

Matthias Rath, M.D. and Aleksandra Niedzwiecki, Ph.D.

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In an adult person, the heart beats approximately 60-70 times per minute...

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25 Million
The human heart beats approximately
25 million times during a lifetime.

PART 1:

What you should know about the heartbeat and arrhythmia

If you have experienced palpitations, rapid heartbeat, dizziness and shortness of breath, it is likely that you have developed an irregular heartbeat, also called arrhythmia. Millions of people suffer from this condition, which most often occurs in people between the ages of 50-70. Approximately 30%-60% of individuals in this age group suffers from some form of arrhythmia at one point in their lives.

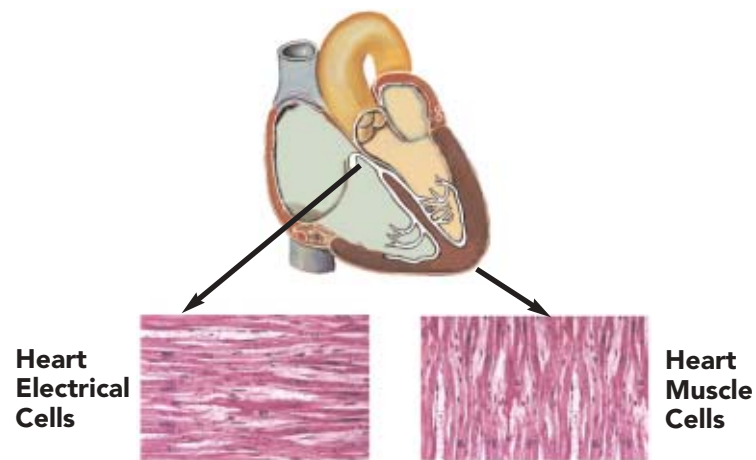
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A. HOW HEART RHYTHM IS REGULATED

The human heart has a defined electrical system made up of cells. This system creates the electrical impulse that is responsible for inducing a heartbeat. The heartbeat assures that blood is pumped continuously under a variety of physiologic conditions, such as when we are asleep and when we are physically active. Each heartbeat represents a remarkable coordinated cellular effort

aimed at maintaining regular and timely contraction and relaxation of the entire heart muscle. There are specific groups of heart cells that generate and conduct the electrical impulses for the regular heartbeat. These cells form two bulks (the sinus node and the AV node), which function like biological batteries. (See Figure 1.) They generate the energy for the heartbeat that assures the coordinated and rhythmical contractions of the entire heart muscle.

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In an adult person, the heart beats approximately 60-70 times per minute. In children and adolescents, the heart rate is higher, beating approximately 85-90 times per minute. You can measure the frequency of your heartbeat by taking your pulse. In patients with heart disease, a doctor will perform a more accurate test called an electrocardiogram (ECG). This test monitors the pattern of heart contractions (See Figure 2.), and it can also identify specific forms of irregular heartbeat, such as:

Tachycardias – frequent heartbeat
(*more than 100 beats per minute*)

Brachycardias – slow heartbeat
(*less than 60 beats per minute*)

Arrhythmias – irregular frequency of heartbeat

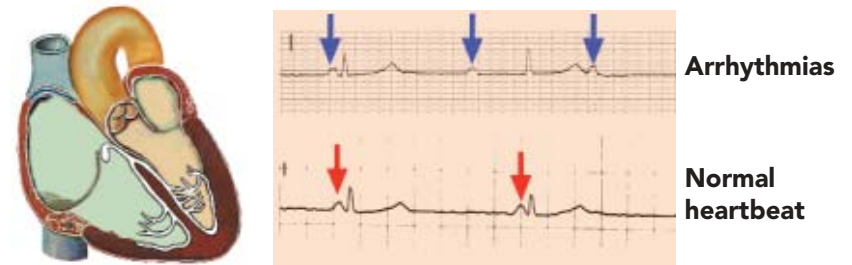


Figure 2.

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B. WHY CONVENTIONAL MEDICINE HAS FAILED IN SOLVING ARRHYTHMIA

In most cases, conventional medicine cannot explain why arrhythmia develops. To cover this fact, the diagnostic term "paroxysmal arrhythmia" was introduced, which simply means the causes of irregular heartbeat are unknown. Because conventional medicine does not recognize the deficiency of bio-energy in the heart muscle cells as the primary cause of arrhythmia, it can only offer symptomatic treatments. These treatments include pacemakers (implanted metal devices that generate electrical impulses), cauterization procedures (electrical burning of a part of the heart muscle to redirect electrical impulses), and anti-arrhythmic pharmaceutical drugs that merely mask symptoms. More significantly, almost all these drugs have severe side effects. The most impor-

tant and frequent of these side effects are the generation of even more irregular heartbeats and, not infrequently, cessation of the heartbeat (sudden cardiac death).

C. THE CELLULAR HEALTH BREAKTHROUGH IN UNDERSTANDING ARRHYTHMIA

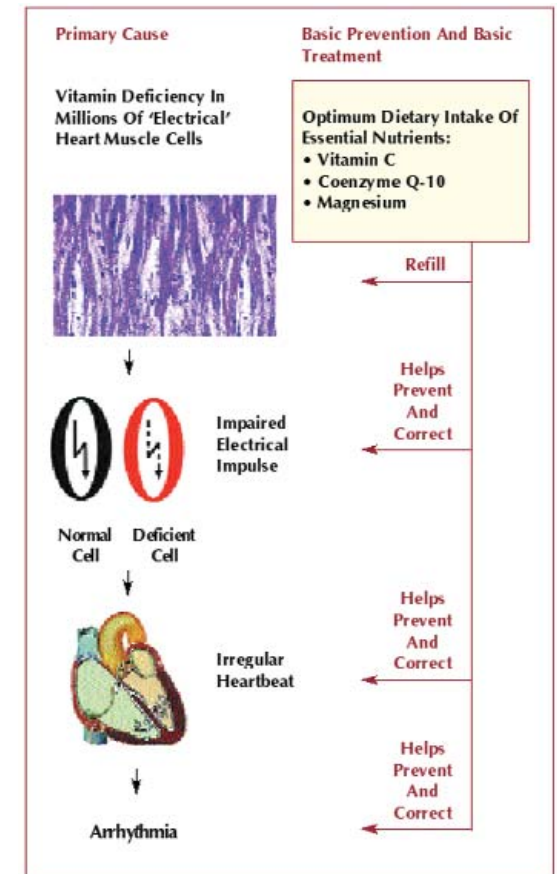
The Cellular Health approach to arrhythmia differs substantially from the conventional medical approach¹. This new understanding about the basis of health and diseases developed by Matthias Rath, M.D. investigates the underlying causes of diseases by analyzing the function and nutritional needs of the body's cells.

In order to generate electricity, the "electrical" cells of the heart need large amounts of bio-energy. Therefore, they require a constant supply of nutrients (bio-catalysts), which are essential for the conversion of food into cellular energy. The most critical among these nutrients are coenzyme Q-10, carnitine, the B vitamins, lysine and vitamin C, along with magnesium, calcium, and potassium.

For optimum biological effect, the nutrients must complement and support each other in synergy. They provide basic biological fuel for optimum function of all cells, but particularly for the electrical cells of the heart, which have extraordinary nutritional demands. If we do not provide our bodies with optimum amounts of these micronutrients, the heart cells will fail to properly generate and conduct electrical impulses. An irregular heartbeat will develop as a result.

It cannot be easily explained why conventional medicine has overlooked this simple fact. Instead of ensuring that the heart receives

an optimum supply of energy-generating nutrients, conventional medicine has relied on mechanical devices and pharmaceutical drugs that have severe side effects. A 10-year-old child can understand that a flashlight cannot operate without "physical" electricity from batteries. In the same way, doctors and patients must accept the fact that the cellular electrical impulses needed for the heartbeat require a continuous supply of "biological" energy.



Causes, prevention and treatment of irregular heartbeat

Cellular Health takes advantage of this logical approach. It has defined a nutrient program that has already improved irregular heartbeat conditions in thousands of patients (www.dr-rath-research.org). In order to provide definite scientific proof about the effectiveness of this program, we conducted a clinical study with the objective of providing indisputable evidence about the efficacy of the Cellular Health approach in patients suffering from arrhythmia.

PART 2:

Importance of clinical research

In order to assess objectively whether the Cellular Health approach works, we have conducted a clinical study with a defined Cellular Health vitamin program in a large population of patients. It is important that everyone understand what a clinical study is and its implications.

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A. WHAT IS A RANDOMIZED, DOUBLE-BLIND PLACEBO-CONTROLLED STUDY?

The highest standard of clinical assessment regarding the efficacy of any treatment is a randomized, double-blind placebo-controlled study. The individual terms are explained as follows:

Randomized: In this type of study, patients are randomly divided into two groups that match each other in regards to age, physical status, and other factors.

Placebo-controlled: One group receives the actual treatment and the other group receives a placebo (a neutral substance, such as sugar pill).

Potassium is an important nutrient needed for generating cellular energy and coordinating heart rhythm. For maintaining regular heartbeat, potassium must stay in balance with sodium and other minerals.

Double-blind: In order to eliminate any bias, neither the investigator nor the participant knows which treatment contains active substances and which treatment contains a placebo. All bottles are coded, and the tablets look identical. The code is broken only after final evaluation of the study.

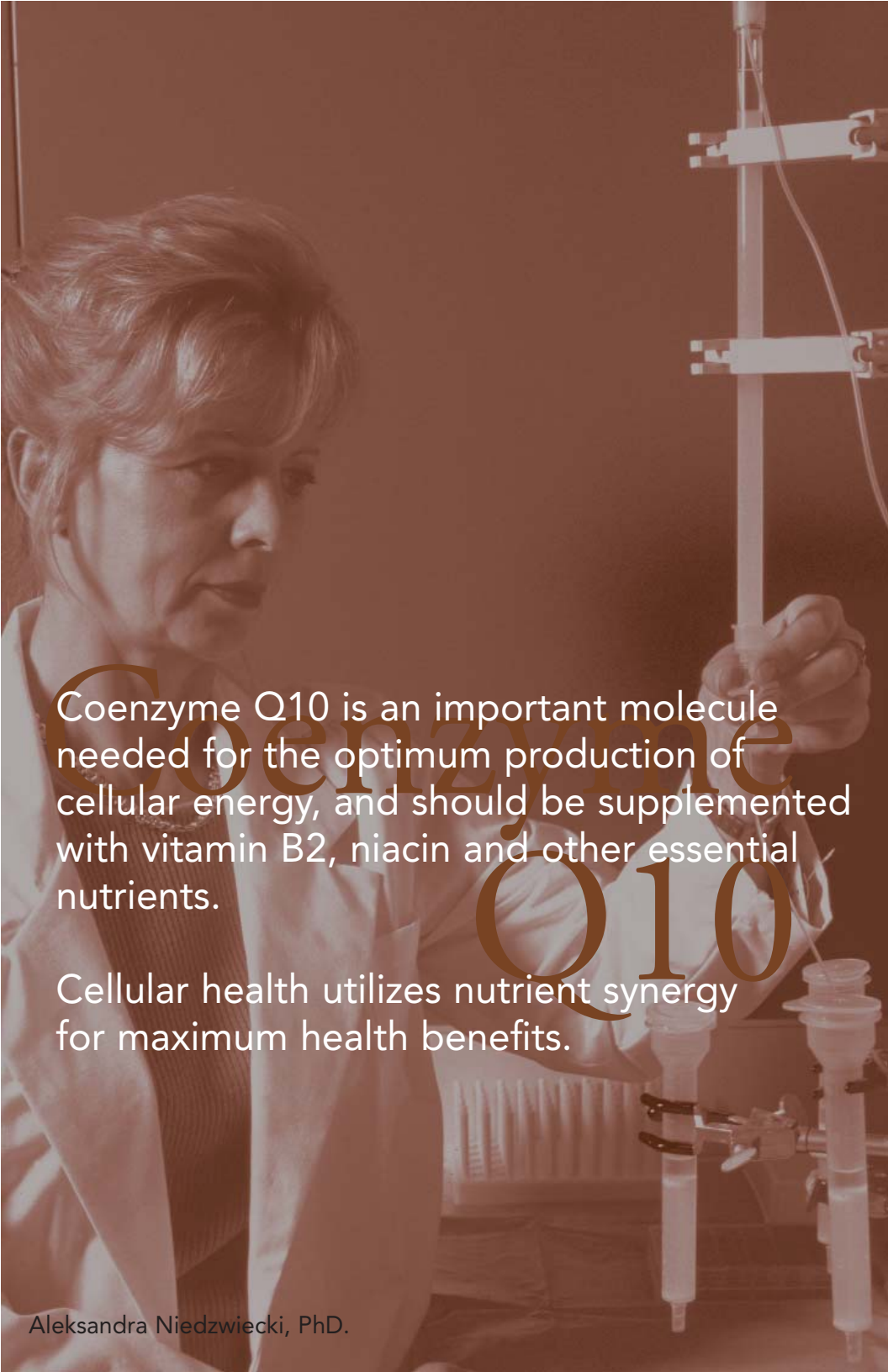
B. HOW EFFICACY OF THE TREATMENT IS DETERMINED (p-VALUE)

The efficacy of the treatment (Dr. Rath's Cellular Health vitamin program) has been evaluated using statistical methods that assess the validity of the results obtained in the treatment and control groups. The probability that the study results have been applied to a large population of patients with this disease has been calculated and expressed as "p-value." The p-value, which is below or equal to 0.05 ($p < 0.05$) confirms that the studied event can occur. If the p-value is lower than 0.05, the significance of the conclusions is higher.

In general, the lower the p-value is, the stronger the validity of the results.


C. WHY IT IS IMPORTANT TO HAVE MANY CENTERS INVOLVED

Each of us is different, and many factors can contribute to the outcome of the treatment. Therefore, by testing the Cellular Health vitamin program on a diverse population of patients, we could reinforce the validity of the results.



Coenzyme Q10 is an important molecule needed for the optimum production of cellular energy, and should be supplemented with vitamin B2, niacin and other essential nutrients.

Cellular health utilizes nutrient synergy for maximum health benefits.

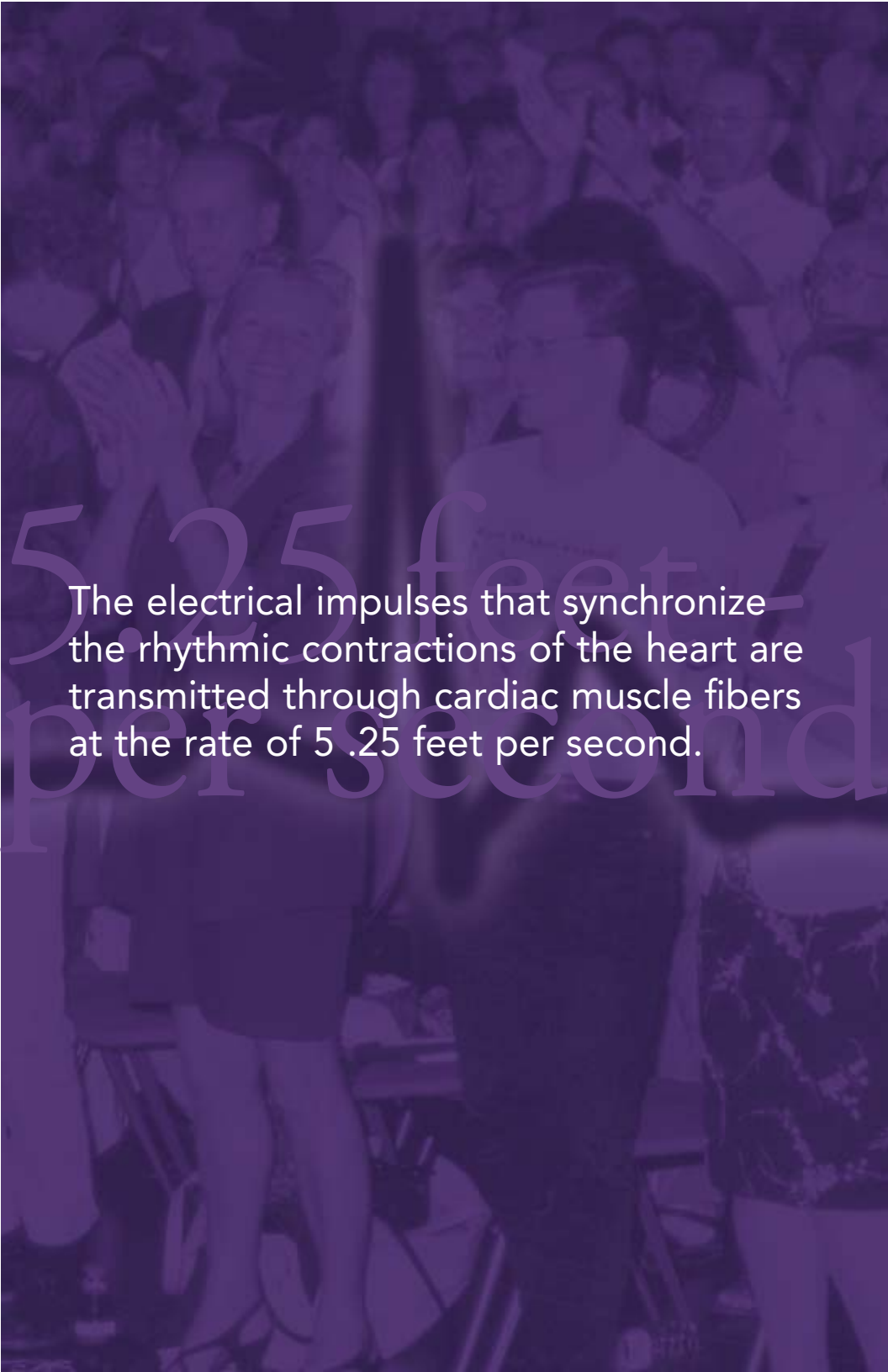


Vitamin C and Lysine are essential nutrients for the production of carnitine. Vitamin C and lysine are not produced in our bodies, and a deficiency of these nutrients leads to an imbalance in cellular energy that can cause irregular heartbeat.

PART 3:

Objective of the study

The purpose of the study was to examine whether the long-term intake of vitamins and other essential nutrients, in addition to a conventional basic therapy, would lead to a reduction in the number of clinically apparent arrhythmic episodes in patients with arrhythmia.



The electrical impulses that synchronize the rhythmic contractions of the heart are transmitted through cardiac muscle fibers at the rate of 5.25 feet per second.

PART 4:

Description of patients, treatment, and study duration

The study involved 140 patients diagnosed with irregular heartbeat (medical term: paroxysmal atrial arrhythmia).

	Vitamin Group <i>(69 patients)</i>	Placebo Group <i>(71 patients)</i>
Age (average)	58 years old	56 years old
Males	38%	42%
Females	62%	58%
Body Weight	78kg/171.83lbs	76kg/167.43 lbs
Treated with Beta-blockers	64%	66%
Treated with Calcium-channel blockers	20%	20%
Cardiac Therapy	20%	21%

17> Patients were randomly divided into two (2) groups: one group taking vitamins (69 patients) and the other group taking a placebo (71 patients). There was no statistical difference in the distribution of males and females in each group. The average age of patients in the vitamin group was 58 years,

and in the placebo group, the average age of patients was 56 years. Arrhythmia was treated with beta-blockers in approximately 2/3 of the patients and with calcium channel blockers in approximately 20% of patients in both treatment groups.

The evaluation at the end of the study revealed that among all patients participating in the trial, 90 strictly adhered to the study protocol. They did not miss visits and followed the vitamin program for 6 months. There were 44 patients in the vitamin group and 46 patients in the placebo group who fulfilled the criteria. Therefore, in order to be completely sure that the observed health effects were due to vitamin intake and not other factors, the final results were evaluated in this group of patients.

A. TREATMENT

Treatment involved daily administration of Dr. Rath’s Cellular Health vitamin program (basic and adjunct) for a six-month period:

Basic Vitamin Program

Vitamins	Minerals	Amino Acids	Coenzymes and Other Nutrients
Vitamin A 1665 IU	Calcium 35 mg	L-Lysine 110 mg	Coenzyme Q-10 7 mg
Vitamin C 600 IU	Phosphorous 15 mg	L-Proline 110 mg	Pycnogenol 7 mg
Vitamin D3 130 IU	Magnesium 40 mg	L-Arginine 40 mg	Inositol 35 mg
Vitamin E 130 IU	Zinc 7 mg	L-Cysteine 35 mg	Pantothenic Acid 40 mg
Vitamin B1 7 mg	Selenium 20 mcg	L-Carnitine 35 mg	Citrus Bioflavonoids 100 mg
Vitamin B2 7 mg	Copper 330 mcg	Biotin 65 mcg	
Niacin 45 mg	Manganese 1.3 mg		
Vitamin B6 10 mg	Chromium 10 mcg		
Folic Acid 90 mcg	Molybdenum 4 mcg		
Vitamin B12 20 mcg	Potassium 20 mg		

Adjunct Vitamin Program

Vitamins	Minerals	Amino Acids	Coenzymes and Other Nutrients
Vitamin C 700	Calcium 13 mg	Taurine 200 mg	Coenzyme Q-1 20 mg
Vitamin E 70 IU	L-Carnitine 160 mg	Biotin 130 mcg	Vitamin B1 15 mg
Pantothenic Acid 40 mg			
Vitamin B2 15 mg			
Niacin 30 mg			
Vitamin B6 4 mg			
Vitamin B12 7 mcg			

PART 5:

Results

A. THE CELLULAR HEALTH VITAMIN PROGRAM DECREASES ARRHYTHMIC EPISODES

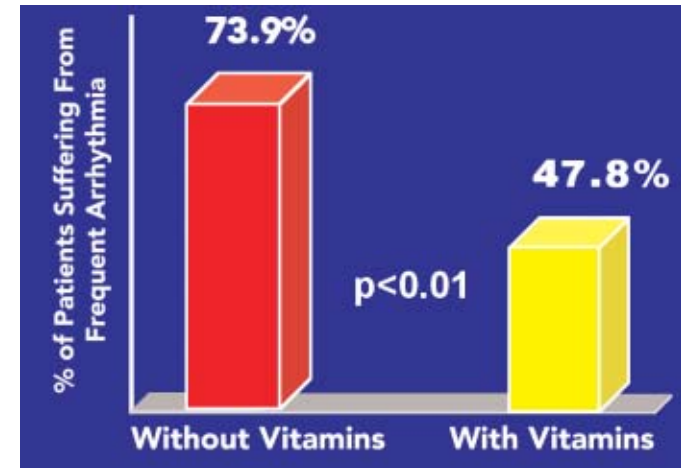


Figure 3.

The most important question of the study was whether the Cellular Health vitamin program could be effective in patients who suffer from severe arrhythmia. Although patients enrolled in our study experienced different severities of irregular heartbeat, the majority of them suffered from frequent arrhythmia, defined as seven (7) or more episodes during the study period. At the end of the study, we analyzed the number of patients who experienced

The cluster of electrical cells that trigger the heartbeat sends an electrical impulse approximately once every 830 milliseconds and needs a constant supply of nutrients to sustain this function.

frequent episodes of irregular heartbeat taking the placebo and the number of patients taking the vitamins.

The results in Figure 3 indicate that the majority of patients (approximately 73.9%) who suffered from arrhythmia had taken the placebo. However, in the vitamin group, remarkably fewer patients reported having arrhythmia (47.8%). This means that approximately 1/3 of patients experienced considerable relief from frequent irregular heartbeats following the Cellular Health vitamin program. This result was statistically significant based on the p-value of 0.01, which means that there is a very high probability that this result could be repeated in other patients.

CONCLUSION:

The study indicates that Dr. Rath's Cellular Health vitamin program can decrease frequent arrhythmia episodes in 30% of patients after six (6) months.

B. THE CELLULAR HEALTH VITAMIN PROGRAM HELPS PATIENTS BECOME FREE OF ARRHYTHMIA

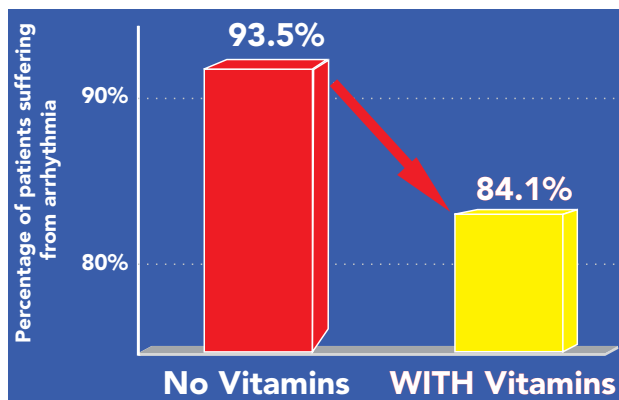


Figure 4.

The results presented in Figure 4 show that 93.5% of patients assigned to a placebo group were still suffering from arrhythmia after six (6) months, despite taking anti-arrhythmic medication during that time. This indicates that pharmaceutical drugs are ineffective in the majority of patients suffering from this condition. However, in the group taking the vitamins, significantly fewer patients experienced irregular heartbeat (84.1%). Therefore, with the use of vitamins, the likelihood of being free from arrhythmia doubled (15.9% in the vitamin group vs. 6.5% in the placebo group).

The results were statistically significant, and the p-value of less than 0.01 indicated that it is highly probable that other persons could experience these results.

CONCLUSION:

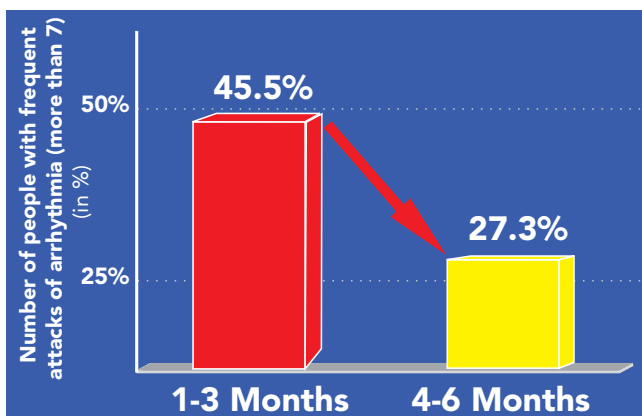
The results clearly show that by using Dr. Rath's Cellular Health vitamin program, the likelihood of being free of irregular heartbeat more than doubles.

C. HEALTH IMPROVEMENTS WITH LONGER USE OF THE CELLULAR HEALTH VITAMIN PROGRAM

Vitamin and other nutrient therapies work in the body by providing optimum nourishment to the cells, thereby improving their function long term. These therapies eliminate the causes of cellular dysfunction and bring long-lasting health benefits. This requires time however, and cellular nutrients rarely bring immediate health effects. In most cases, patients report that they experience the beneficial effects of nutrients after a few weeks of their intake, and

health improvements continue with longer use of the vitamin program. Therefore, we have determined that there are benefits in the long-term use of the Cellular Health vitamin program for arrhythmia.

- **Frequency of arrhythmia attacks decreases with longer use of the Cellular Health vitamin program.**



Fewer experiences of arrhythmia with longer vitamin use

Figure 5.

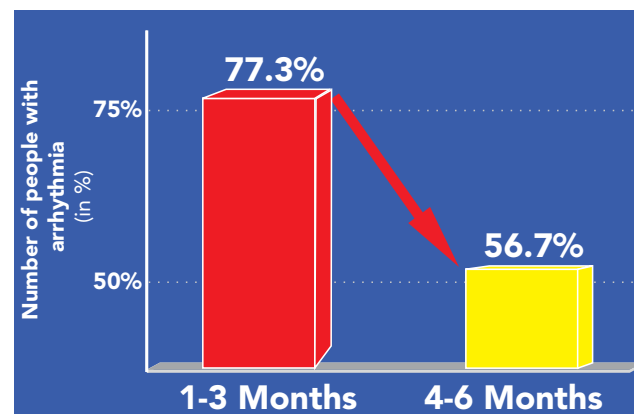
During the first three (3) months of the study, almost half of the patients (45.5%) experienced seven (7) or more arrhythmia attacks. However, during the second half of the study, the number of people complaining of frequent arrhythmic episodes significantly decreased, and only approximately 27.3% of patients reported that arrhythmia was still present. (See Figure 5.)

CONCLUSION:

This steady decrease in the occurrence of irregular heartbeat suggests that with extended use of the Cellular Health vitamin program (longer than 6 months), even patients with more

advanced stages of the disease can expect improvements in their heart conditions.

- **More people are completely free from arrhythmia with longer use of the Cellular Health vitamin program.**



Improved chance of being free from arrhythmia!

Figure 6.

In the first three (3) months of the study, approximately 77.3% of patients who took vitamins reported episodes of irregular heartbeat. At the same time, almost 90% of patients taking the placebo suffered from arrhythmia. Therefore, taking vitamins gave patients an advantage during the first three (3) months of the study.

During the second half of the study (months 4-6), many more patients taking the vitamins reported that they did not experience any arrhythmia at all. The results show that by being a regular vitamin user, the chances of being arrhythmia free almost doubled. (See Figure 6.) Approximately half of the patients in the vitamin group did not experience irregular heartbeat with longer vitamin intake (4-6 months).

These results confirm the health benefits of long-term vitamin use. The observed trend also suggests that by continuous adherence to the Cellular Health vitamin program, many more patients can be arrhythmia free. This also confirms that, due to vitamin intake, approximately 70% of study participants experienced an improvement in their health conditions.

CONCLUSION:

This remarkable result confirms that the longer vitamins are used, the better one's health becomes!

D. THE CELLULAR HEALTH VITAMIN PROGRAM HAS POSITIVE EFFECTS ON GENERAL WELL-BEING AND OTHER HEALTH ASPECTS

	With Vitamins	Without Vitamins
General health	+ 4.0	- 0.3
Vitality	+ 9.5	+ 2.8
Mental health	+ 7.4	- 1.6
TOTAL SCORE	90	47

Figure 7.

Arrhythmia patients not only suffer from the consequences and fear of experiencing heart dysfunction, but also from deteriorating

health and a gradual diminishing of their quality of life. To a large extent, this is associated with drug side effects and the realization that a cure for this health problem is not available.

Our study took this important aspect into account, and we evaluated how vitamin intake affected patients' general well-being and quality of life. The results were compiled using a standardized quality of life assessment questionnaire, which is used in all types of human studies. The questionnaire used in our study evaluated 36 different parameters that described the physical function of patients, level of pain, emotional status, vitality, perception of general health and other aspects.

The results of this questionnaire were analyzed by a computer based on a grading system assigned to each question that allowed for quantitative comparison of the results. The assessment of quality of life in our study was very encouraging for vitamin users. Patients who took Dr. Rath's Cellular Health vitamin program scored almost twice as high on a quality of life assessment questionnaire than patients who took the placebo.

In some aspects, such as in the perception of general well being and mental health, there were significant improvements at the end of the study. At the same time, patients taking the placebo reported feeling worse at the end of the study than at the beginning. Patients on the Cellular Health vitamin program outperformed placebo patients approximately four (4) times in vitality and physical function. (See Figure 7.) Particular benefits were noted in improved mental health. Patients on vitamins performed better, while the mental health of patients taking the placebo worsened.

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Patients taking anti-depressants, certain antibiotics, cardiac medications or tamoxifen are at risk of arrhythmia and even cardiac death.

Hennessy S et al in *British Medical Journal* 2002, 325, 1070

Curtis LH et al in *American Journal of Medicine* 2003, 114, 135 - 141)

PART 6:

Conclusions

The results of this randomized, double-blind placebo-controlled study conclusively document the effectiveness of vitamins and other essential nutrients in controlling irregular heartbeat, a condition for which conventional medicine does not provide a solution.

These health benefits were achieved by addressing the underlying cause of arrhythmia, which is the deficiency of nutrients that generate bio-energy in the heart muscle cells. The Cellular Health vitamin program used in the study provided nutrients in the right composition and proportion, which helped achieve the following benefits within six (6) months:

- Statistically significant decrease in the frequency of clinically apparent arrhythmic episodes.
- Statistically significant increase in the number of people without arrhythmic episodes.
- Statistically significant time delay before the first arrhythmic episode appeared.
- Increased health benefits of this vitamin program with longer time of use, which should extend beyond six (6) months.

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- Stronger improvement in general health and quality of life, and in particular, in mental health.

This safe and effective Cellular Health vitamin program provides long-lasting health benefits for patients with arrhythmia, without the side effects associated with the use of pharmaceutical drugs. It is also cost effective.

This conclusion is especially important since recent large clinical trials have confirmed that anti-arrhythmic drugs, which are used by more than 1.5 million Americans and many more people in Europe and other countries, do not offer health benefits and worse still, they increase the risk of serious complications, including death. In 1989, a study using anti-arrhythmic drugs in patients who had experienced heart attacks was ended early when preliminary results showed the risk of death was two and a half times (2.5) greater in patients taking drugs.

In 2002, two large studies, one conducted in Canada and the other in the Netherlands, provided similar evidence². The six-year study, conducted with more than 4,000 patients, showed higher death and hospitalization rates among patients on anti-arrhythmic drugs. This included drugs that affect heart rate, such as dioxin, beta-blockers, and calcium channel blockers. The European study came to the same conclusion, and it also found that women taking anti-arrhythmic medications faced a higher risk of heart failure, stroke, and other medical events than men.

This study shows that arrhythmia can be controlled in a natural way by eliminating the underlying causes of this condition.



Matthias Rath, M.D. and
Aleksandra Niedzwiecki, Ph.D.

PART 7:

About Matthias Rath, M.D. and Aleksandra Niedzwiecki, Ph.D.



MATTHIAS RATH, M.D.

Dr. Rath, a graduate of Hamburg Medical School, is an internationally respected physician and research scientist who has led breakthroughs in the natural control of cancer, cardiovascular disease, and other chronic health conditions.

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Dr. Rath's clinical research proves that the cause of most common diseases is actually long-term nutrient deficiencies and his Cellular Health approach defines optimum nutrition for the body's cells as a means to prevent and control today's most common diseases. He established Dr. Rath's Health Alliance so that people everywhere can take advantage of his scientific discoveries in Cellular Health and participate in the battle for vitamin freedom.

Dr. Rath's work has been published in many professional journals, including in the *Proceedings of the National Academy of Science*, the *Journal of Orthomolecular Medicine*, and *Arteriosclerosis*.

ABOUT ALEKSANDRA NIEDZWIECKI, PH.D.

Aleksandra Niedzwiecki, Ph.D. received her doctorate degree in biochemistry from the University of Warsaw in Poland. Dr. Niedzwiecki has held research and faculty positions at Rockefeller



University in New York, the University of Toronto, and the University of Warsaw.

During her career, she has worked directly with the two-time Nobel Laureate Linus Pauling and G.M. Edelman, who was awarded the 1972 Nobel Prize in medicine/physiology. Dr. Niedzwiecki's research has been pub-

lished in over 70 professional journals, book chapters, and scientific publications. For the last 12 years, she has worked with Dr. Rath in the research and development of Cellular Health approaches.

PART 8:

Acknowledgments

This study was conducted in 35 health centers located in Germany. We are grateful to Mr. Frank Kock for his assistance in the study.

PART 9:

Literature

1. M. Rath. *Why Animals Don't Get Heart Attacks, But People Do*, MR Publishing, Inc. 2001.
2. AFFIRM Investigators. A comparison of rate control and rhythm control in patients with atrial fibrillation. 2002. *New England Journal of Medicine*. 347,1825-1833.

This study was possible because of the support of thousands of patients who have already benefited from Dr. Rath's Cellular Health Programs. We thank each one of our supporters for their commitment to disseminating Cellular Health information to others.