A Clinical Study: Modifying Nagalase with Glycome

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ABSTRACT

Thirty-three adult patients at the Turtle Healing Band Clinic ("THBC") in Las Vegas, Nevada had positive laboratory responses observed when treated with Glycome ("Nagalase modifier")[1] both: (1) orally; and (2) intravenously.

Material, Methods, and Subjects

The 33 THBC patients were subjects in the study if they were found to have: (1) Elevated Epstein-Barr Virus ("EBV") Early Antigen; (2) Cancer with an elevated Anti-Malignin Antibody in Serum ("AMAS") test; and/or (3) Elevated Nagalase without EBV or cancer by AMAS; and (4) were adults >18 years of age. The study was conducted over 18 months (October 2017 to April 2019).

NAGALASE

(A Test Used to Monitor Cancer and Viral Infections)[2]

The Nagalase test measures the activity of an enzyme α-N-acetylgalactosaminidase (Nagalase) in blood, an extracellular matrix-degrading enzyme that is secreted by cancerous cells in the process of tumor invasion. It is also an intrinsic component of the envelope protein of virions, such as HIV and the influenza virus, secreted from virus-infected cells.[3,5,6]

Nagalase deglycosylates the vitamin D3-binding protein DBP (also known as Gc-protein). Gc-protein, which contains three sugars, is the precursor for the major macrophage-activating factor (MAF). By complete deglycosylation, Gc-protein can no longer be converted to MAF. Normally, MAF is produced from the Gc-protein by sequential removal of the galactose and sialic acid without touching the remaining sugar N-acetylgalactosamine. Macrophage activation for phagocytosis and antigen presentation is the first step in the immune development cascade. Lost precursor activity, therefore, leads to immune suppression.

Increased Nagalase activity has been detected in the blood of patients with a wide variety of cancers like cancer of the prostate, breast, colon, lung, esophagus, stomach, liver, pancreas, kidney, bladder, testis, uterus, and ovary, mesothelioma, melanoma, fibrosarcoma, glioblastoma, neuroblastoma, and various leukemias.[3,5,6] For various types of tumors, various levels of Nagalase activity were found.[9] It appears that the secretory capacity of individual tumor tissue varies among tumor types depending upon tumor size, staging, and the degree of malignancy or invasiveness.[8] Increased nagalase activity has not been detected in the blood of healthy individuals.[3]

Nagalase activity is directly proportional to viable tumor burden.[3,4] Studies correlating Nagalase levels with tumor burden suggest that the measurement of this enzyme can diagnose the presence of cancerous lesions below levels detectable by other diagnostic means.[3] In research studies, Nagalase activity decreased to near tumor-free control levels one day after surgical removal of primary tumors from cancer patients, suggesting that the half-life of nagalase is less than 24 hours.[3,8] The short half-life of Nagalase is valuable for prognosis of the disease during various therapies.[3,7]

Nagalase Test indications

Nagalase in blood is a sensitive test for monitoring the efficacy of therapy in cancer and certain viral infections, including HIV and recently HSV-1/2. Because of the short half-life of Nagalase, the method is suitable for monitoring various types of therapy. The great sensitivity of the test may help the physician/oncologist in obtaining a better understanding of the therapy and to fine-tune the treatment. **NOTE:** The values may be affected by certain drugs used in the five days preceding blood draw. Drug use must be indicated on the Questionnaire submitted with the Requisition Form.

NAGALASE ORAL TREATMENT PROTOCOL

One-Month Supply

- Orasal (Glycome) liquid (2 bottles + 1 pump);[10]
- pHenomenal liquid (1 bottle);
- React/Impact capsules (1 bottle); and
- Alkalign capsules (1 bottle).

Orasal and pHenomenal Instructions

1. Unless you already have one, purchase a 1-liter bottle with a mouth opening of at least 1.5 inches.[11]
2. Fill the 1-liter bottle ½ with good quality drinking water. [**Note:** Do not use distilled or Kangan water).][12]
3. Place pump in Orasal bottle and put in exactly eight (8) squirts of Orasal into the 1-liter bottle. As an alternative, add one (1) tablespoon (15 ml) of Orasal.[13]
4. Add two (2) tablespoons (30 ml) of pHenomenal to the 1-liter bottle.
5. Fill 1-liter bottle the rest of the way with water, cap tightly, and place in the refrigerator overnight.
6. The following day, drink the 1-liter bottle throughout the day and finish it.
7. Repeat steps 2-6 each 24-hour period.

React/Impact Instructions

One (1) capsule three times daily.

Alkalign Instructions

Two (2) capsule three times daily.

NAGALASE IV TREATMENT PROTOCOL

Salacinium

One (1) 10 ml vial administered intravenously for a series of fifteen (15) treatments

AMAS TEST BACKGROUND

("Anti-Malignin Antibody in Serum")[14]

Detection of cancer before the presence of any signs or symptoms by means of a simple blood test is now available. This milestone signals the beginning of a new molecular approach to cancer—one that need not wait for billions of cancer cells to form a lump which can be felt or X-rayed before cancer is diagnosed and treated. The test is called AMAS ("Anti-Malignin Antibody Serum"). The elevation in the concentration of this antibody is associated at high accuracy with the occurrence of cancer cells in the body regardless of the cell type or location.[15]

As an example, one patient had been followed with AMAS tests every 2 months because he was at increased risk due to previous colon cancer. The AMAS concentration increased from normal values,

through borderline to markedly elevated values. As a result, other tests were done to localize the cancer. Sigmoidoscopy did not show recurrent colon cancer. The prostatic specific antigen (PSA) was then found to be markedly elevated. Needle biopsy of the prostate gland revealed cancer. Hormonal treatment successfully reduced both the AMAS and the PSA to normal values. This method represents histopathology-confirmed symptomatic cancer diagnosis and treatment by molecular means that is now available.

At the International Society of Preventive Oncology in Nice, France, Drs. Samuel and Elenore Bogoch reported on a study of 82 breast cancer patients who were followed with repeated AMAS tests after cancer surgery performed one to 30 years previously.[16] 67 of these patients were asymptomatic and in remission—the AMAS test was normal in all 67! On the other hand, 15 of these patients had a persistence or recurrence of their cancer; part of a larger blind study of AMAS in 1,175 cases of benign and malignant breast disorders, and 3,078 healthy normal controls.

All of the data from both Bogoch et al., and from the independent study performed by SmithKline Laboratories, support the fact that AMA ("Anti-Malignin Antibody") in blood serum is elevated almost regardless of the site or cell type of the malignancy. This is because AMA is a general transformation antibody, not just for one type of cancer. For serum determined within 24 hours of being drawn, the false-positive and false-negative rates are less than 1% (specificity and sensitivity greater than 99%). For stored sera false positives are 5% and false negatives 7% (3,315 double-blind tests of patients and controls).

AMA is the antibody to Malignin, a 10,000 Dalton polypeptide which has been found to be present in most malignant cells regardless of cell type or location. Unlike tests such as CEA, which measure less well-defined antigens whose serum levels tend to be inconstant but elevated late in the disease, the AMAS test measures a well-defined antibody whose serum levels rise early in the course of the disease. In some cases, the AMAS test has been positive (elevated) early (i.e., 1 to 19 months before clinical detection). On the other hand, since antibody failure often occurs late in malignancy, elevated antibody is then no longer available as evidence of the presence of antigen. Therefore, late in the disease, the AMAS test cannot be used as a diagnostic aid although it may still be a useful tool for monitoring the disease.

A common clinical situation involves signs or symptoms suggesting a disorder which may or may not be malignant. While neither AMAS nor any other clinical laboratory test can be itself answer this question, AMAS test results may help the physician in the diagnostic process. The double-blind clinical studies in the graph above include non-cancer control groups and malignancies of the breast, lung, and brain as well as melanomas, lymphomas, leukemias, and colorectal malignancies. Also included are smaller numbers of malignancies of the larynx, uterus, cervix, ovary, anus, stomach, esophagus, prostate, bladder, urethra, kidney, testes, thyroid, and skin and fibrosarcoma, leiomyosarcoma, osteogenic sarcoma, rhabdomyosarcoma, mesothelioma, liposarcoma and hemangioblastoma.

Cancer of the cervix of the uterus is one of the few situations where the cancer can actually be shown in humans via microscopic examination in the PAP smear to develop from the earliest premalignant stages to a frankly malignant state. Periodically repeated AMAS tests are now being used in previous cancer, in smokers, or in people over 50 years of age. AMAS is approved by Medicare. Further, The American Cancer Society states that as many as 35% of all cancer deaths might be saved by early detection. If feeling a lump or observing an unusual shadow on a mammogram, followed by early treatment, can lead to the saving of 35% then catching cancer even earlier should provide further improvement in survival.

Both monitoring data and the retrospective survival study of 511 cancer patients have shown that the AMAS test may be useful in indicating disease progress and prognosis. In this situation, AMAS is a test

in all types of cancer both to monitor remission after treatment, and to look for early signs of recurrence. Thus, in known cancer patients, when the immune response is good as evidenced by high antibody levels, the prognosis is good; and when the antibody level falls, the prognosis is poor.

AMA is the first general cancer antibody found to relate to patient survival. Thus, the test may be useful as an adjunct to standard (sometimes less accurate) staging information such as the spread of malignancy beyond the capsule of the primary organ and the presence of metastases in lymph nodes, or general symptoms such as anemia, weight loss, and fatigue. AMA is elevated in 93-100% of cases in which active non-terminal malignancy is the clinicopathological diagnosis. Overall asymptomatic ("false") positives are 5% in sera kept frozen more than 24 hours, but less than 1% in serum determined within 24 hours after blood is drawn. AMA is normal in 96% of cancer patients who no longer have evidence of disease.

The low false-positive and false-negative rates (<1% on repeat determinations of 24-hour serum) have permitted successful screening in selected high-risk populations, as in chemical workers and in the preclinical detection of cancer in 2.3% of medical-surgical cases. However, the efficacy of screening in larger normal populations has yet to be determined. A normal AMA level can occur in non-cancer, in terminal cancer, and in successfully treated cancer in which there is no further evidence of disease. Clinical status must be used to distinguish these states. As in all clinical laboratory tests, the AMAS Test is not by itself diagnostic of the presence or absence of disease, and its results can only be assessed as an aid to diagnosis, detection or monitoring of disease in relation to the history, medical signs and symptoms and the overall condition of the patient.

RESULTS

Preliminary results for 33 patients showed:

(1) 82% positive response in lowering Nagalase levels for patients who used the oral protocol for 1 month;[17,18]
(2) 56% initial increase in Nagalase from baseline levels for patients who received a Nagalase modifier IV;[19]
(3) 91% positive response in lowering Nagalase for patients who used the oral protocol for ≥2 months;
(4) 80% initial positive response in lowering AMAS levels from baseline Net-TAG levels in cancer patients; and
(5) 100% positive lowering of AMAS Net-TAG levels for cancer patients who used oral protocol for ≥2 months.

CONCLUSION

The Nagalase modifier used in this study was found to have a strong positive effect on lowering Nagalase blood levels in both viral and cancer patients as well as AMAS blood levels in cancer patients.

REFERENCES and NOTES

1. Perfect Balance, 218 Main Street, Suite 295, Kirkland, Washington 98033.
2. Health Diagnostic Research Institute, 540 Bordentown Avenue, Suite 2300, South Amboy, New Jersey 08879.
3. Korbelik M, VR Naraparaju, N Yamamoto. "The value of serum alpha-N-acetylgalactosaminidase measurement for the assessment of tumor response to radio- and photodynamic therapy." Br J Cancer, 77:1009-1014, 1998.

4. Reddi AL et al. “Serum alpha-N-acetylgalactosaminidase is associated with diagnosis/prognosis of patients with squamous cell carcinoma of the uterine cervix.” Cancer Lett, 158:61-64, 2000.
5. Yamamoto N and M Urade. “Pathogenic significance of alpha-N-acetylgalactosaminidase activity found in the hemagglutinin of influenza virus.” Microbes Infect, 7:674-681, 2005.
6. Yamamoto N. “Pathogenic significance of alpha-N-acetylgalactosaminidase activity found in the envelope glycoprotein gp160 of human immunodeficiency virus Type I.” AIDS Res Hum Retroviruses, 22:262-271, 2006.
7. Yamamoto N, H Suyama, N Yamamoto. “Immunotherapy for prostate cancer with Gc protein-derived macrophage activating factor (GcMAF).” Transl Oncol, 1:65-72, 2008.
8. Yamamoto N et al. “Therapeutic efficacy of vitamin D3-binding protein-derived macrophage activating factor for prostate, breast and colon cancers.” Cancer Res Proc, 38:31, 1997.
9. Yamamoto et al. Deglycosylation of serum vitamin D3-binding protein leads to immunosuppression in cancer patients.” Cancer Res, 56:2827-2831, 1996.
10. Avoid taking antioxidants with the Glycome products (e.g., Vitamins A, C, D, E, Beta-Carotene, etc.).
11. Mouth opening size is for the convenience of filling the bottle.
12. Brita filter is acceptable.
13. One bottle of Orasal should last approximately 2 weeks.
14. Oncolab, Inc., 36 Fenway. Boston, Massachusetts 02215.
15. AMAS review published by the National Cancer Institute, J. Cell Biochem, 19:172-185, 1994).
16. Cancer Detection and Prevention, 20:507-508, 1996.
17. See “Nagalase Modifier”.
18. See “Nagalase Protocol”.
19. This result is theorized to be the result of a "die-off" phenomenon due to saturation of the body with an intravenous Nagalase Modifier (a.k.a. Salicinium, or the IV form of Orasal) as subsequent levels improved.