Katharina Voss, Copyright 2018 (Author of a German textbook on ME entitled
"ME - Myalgische Enzephalomyelitis vs. Chronic Fatigue Syndrom: Fakten Hintergründe Forschung", tredition 2017)

Saturday, June 9th, 2018
Doctor Inquiries -
My Therapy Regime for Antiretroviral Treatment of Myalgic Encephalomyelitis

Introduction:

I receive numerous inquiries from doctors at home and abroad who have been made aware of my blog post about the successful antiretroviral therapy (ART) of my ME afflicted daughter by their patients suffering from Myalgic Encephalomyelitis (ME). These physicians are interested in my therapy regime developed by me for my daughter and sometimes also want to clarify further questions about ART for ME.

Until now I responded to these questions individually. In order to spare myself this constantly growing (unpaid) work in the future, but above all to also involve patients in this therapeutic concept and make my method comprehensible to them, I have now decided to publish my so far very successful treatment strategy. Unfortunately, I also had to realize that not all doctors who contacted me have been taking my notes on the urgency and frequency of blood and urine testing seriously. My proposals on dosage and accompanying treatments do not seem to always be taken seriously either. By publishing my concept, every patient can now get an idea and decide for oneself whether to accept my suggestions.

As a matter of principle, however, I would like to state in advance that these are by no means medical recommendations or advice, but merely suggestions based on the experience I and other patients have gathered and on my intensive research of literature on the subject. In addition I refer to my disclaimer.

ART for ME:

Treatment with antiretroviral drugs (ARV) for ME is above all based on research by Judy Mikovits et al., who - like several other researchers - found a human gamma-retrovirus (HGRV) in the blood of ME patients (see my blog post). Eligible ARVs for treatment of HGRV infection are AZT, Tenofovir and Raltegravir. The profile of side effects of AZT, however, is much more severe than that of the reverse transcriptase inhibitor Tenofovir. Since the proliferation of infected cells must first be stopped, it is advisable - at least according to Dr. Judy Mikovits and the experience of patients treated with ART - to start treatment with **Tenofovir** and add the integrase inhibitor **Raltegravir** later, if required at all.

Some patients treated by Dr. John Chia also reported successful ART with nucleoside reverse transcriptase inhibitor Lamivudine. In addition, I received reports of patients who have been successfully treated with Truvada, a combination drug containing Tenofovir and used in Pre-exposure Prophylaxis (PrEP).

Since retrovirus research in ME is undermined for various reasons (see my book ME - Myalgische Enzephalomyelitis vs. Chronic Fatigue Syndrom: Fakten Hintergründe Forschung), there are unfortunately no tests that could serve as a reliable indicator for ART. One could potentially look for reduced NK cell activity, a defect in antiviral enzyme RNase L, increased HHV-6 titers and proliferation of Anellovirus in plasma.

Katharina Voss, Copyright 2018 (Author of a German textbook on ME entitled
"ME - Myalgische Enzephalomyelitis vs. Chronic Fatigue Syndrom: Fakten Hintergründe Forschung", tredition 2017)

While such tests may facilitate the identification of responders, this is hardly a certain method, as valid examinations are still absent.

Even SG-PERT, a testing procedure that quantifies reverse transcriptase activity and can, for example, be performed at the Nationales Referenzzentrum für Retroviren, unfortunately does not indicate whether one is a responder. This was demonstrated by our and other patients' experiences. Perhaps this test does not detect the possibly ultra low-level activity of an HGRV reverse transcriptase enzyme?

Even if one is not a supporter of the retrovirus causation hypothesis, Tenofovir could still be contemplated as a treatment option for ME patients, as it has immunomodulatory properties and acts as an anti-inflammatory agent - at least in patients with proven retrovirus infection.

However, since experience to date shows that an integrase inhibitor usually needs to be added after a while in order for the patient to continue making progress, there is some evidence to suggest that the efficacy of Tenofovir in ME patients is due less to its anti-inflammatory and immunomodulatory properties than to inhibition of retrovirus replication.

ART for ME: Preconditions

According to the current state of knowledge, it can generally be assumed that only those patients who meet the International Consensus Criteria will benefit from ART (Carruthers et al. 2011, here a short version of the criteria in German). These are patients whose main symptom is not tiredness or generalized fatigue, but a pathological muscle exhaustibility resulting in neuro-immunological exacerbation (PENE) even after slight exertion. (More on ME in my book)

In any case, if the attending physician is inexperienced in treatment with ART, cooperation with an HIV specialist is essential in order to better assess potential risks and side effects.

Laboratory controls:

Before starting any monotherapy with an ARV, it is imperative that both an HIV test and a Hepatitis B test are carried out. This is important not only to prevent the development of drug resistance in the case of actual infection with HIV or Hepatitis B, but also to provide documentation to health insurance if one intends to lay claim to payment of Viread.

The following further examinations are necessary before therapy and for follow-up (since I do not guarantee the comprehensiveness of my information and some patients require additional examinations, any necessary examinations should again be discussed with an HIV specialist):

Gamma-GT
GOT
GPT
GFR
creatinine
Large blood count
erythrocytes

leukocytes
thrombocytes
lymphocytes
CD3 cells
CD4 cells
NK cells
potassium
Blood sugar tests
Blood fat levels (total cholesterol and triglycerides, HDL and LDL cholesterol)
Bone metabolism (determination of calcium, phosphate, total protein, albumine in blood)

In order to determine kidney function, a 24-hour urine collection test (+ blood serum) is recommended.

All these values must be measured again after 4 weeks of treatment and thereafter be checked at regular intervals, which - in case of known risk - must be carried out either closely or every one to two or three months.

When evaluating lab parameters, it must furthermore be taken into account whether and if so which dietary supplements patients are taking.

My therapy plan:

Now, these are the details of my special treatment concept, which is based on Judy Mikovits', Harvey Alter and Ila Singh's research as well as primarily on my own literature research and considerations. The concept I developed is mainly based on two pillars, on the one hand the **unorthodox handling of dosage** and on the other hand some very specific **additional phytotherapeutic treatments**.

1. Dosage

First, on the unusual handling of dosage, one of the two pillars of my therapy concept. In other retroviral infections, ART is usually started at the full dose that is maintained as long as the patient tolerates the drug well and no resistancies develop. This approach does not seem to work well for severely ill ME patients - according to our experience. The patient who is responding to the drug then does make extremely rapid progress, but also experiences unbearable side effects at the immunological and neurological levels, which eventually force him to discontinue therapy. Subsequently, all progress disappears relatively quickly again, so that the patient is soon as bad as before or - in the case of a progressive course of the disease - increasingly worse again.

In contrast to HIV-infected individuals, in which the illness has usually not yet fully broken out when they start treatment, in a severely ill person with ME the full picture of the illness is already apparent. This is probably why these patients are more likely to develop an immune reconstitution syndrome (IRIS) when starting therapy, just like previously untreated HIV-infected patients who have already developed AIDS. In the latter, very low CD4 cell counts, a high viral load prior to commencement of therapy and rapid decrease thereof under treatment seem to be predictors of IRIS. This could be similar in ME patients.

Katharina Voss, Copyright 2018 (Author of a German textbook on ME entitled
"ME - Myalgische Enzephalomyelitis vs. Chronic Fatigue Syndrom: Fakten Hintergründe Forschung", tredition 2017)

IRIS is marked by an aggravation of the infectious or inflammatory process, induced by the start of treatment with ART. Regeneration of the immune system reveals latent infections, which often could not be identified or objectivized beforehand, and may cause severe immunological and neurological symptoms. This is especially applicable for the severely ill who begin treatment at full dosage. Slow, low dose introduction of drugs and dietary supplements is recommended for ME anyway, and it is apparent that the severely ill ME patient's organism will also need to gradually get accustomed to ART in order to avoid severe side effects that could lead to discontinuation of therapy.

The basis for the idea of an unorthodox approach to dosage was the certainty that gamma retroviruses found in the blood of ME patients by some researchers - unlike HI viruses - replicate only very slowly (cf. my book).

That is why - these were my thoughts - resistancies cannot develop as quickly. It was probably a hitherto unique experiment which we started, and it was associated with great risk, because no doctor and no scientist could tell us for sure whether a resistance would not in fact develop when starting at a low dose. To my knowledge, none of the few ME patients who undergo ART had tried this before. But our experiment was worth it, because it shas been successful.

However, it is important to know that, according to Dr. Mikovits, one can only start with a low dose if there is no **acute** co-infection, e.g. because of the risk of resistance emergence. If an acute co-infection is present, it is probably advisable to fight it first and/or to enter ART at full dose, whereas however side effects, as explained, can turn out violently in severely ill patients.

Dosage details:

Our experience has shown that severely ill ME patients (Bell scale 0) can apparently start safely with an eighth of a Tenofovir tablet - in our case it was **Viread**, which contains 245mg Tenofovir disoproxil per pill. Of course, I cannot guarantee whether this will apply to all patients; unfortunately, use of this drug is and for the time being remains an experiment that many do not want to forego, because they have their backs to the wall and are heading for a certain end without treatment.

According to our findings, one can take a lot of time with the increase in dose and wait in peace until the organism has adapted to every further small increase. In our case, it took seven months to reach full dose. Patience is therefore required, because significant improvements only occur in most responders after reaching full dose. However, after three to four months of daily intake of 245mg, progress should become apparent. (There is, however, also talk of a patient who only experienced significant improvements after 6 months of Truvada application.) If it has not occurred by then, it can be assumed that the drug is not effective in a patient. The improvement in condition is incidentally often wave-like, with ups and downs, but the overall tendency should be an upwards one.

Moderately and mildly ill patients can - according to the experiences of other patients described - presumably enter therapy at a higher dose with rapid increase or immediately at the full dose of 245mg. In that case, faster progress is to be expected if the drug is effective. But even in these patients, significant improvements are usually only to be expected after three to four months (cf. p. 3 here).

Katharina Voss, Copyright 2018 (Author of a German textbook on ME entitled
"ME - Myalgische Enzephalomyelitis vs. Chronic Fatigue Syndrom: Fakten Hintergründe Forschung", tredition 2017)

The first small improvements are sometimes noticeable after a shorter period of time - in some patients also at low doses - but mostly concerning physiological processes, such as improved sleep quality and a return to an intact day/night rhythm, improved blood circulation in the limbs, fewer food intolerances, etc., but sometimes also concerning neurosensory symptoms, e.g. a reduction in sensory hypersensitivity.

Risks and side effects:

Patients and doctors must inform themselves about the risks and side effects of ART. Relatively little can be said about side effects, since they differ individually in ME patients. The most important side effects can be found listed in the medication's package inserts. All ME patients have to expect side effects, those affected more severely even more so particularly. However, the mildly and moderately ill should also be prepared for side effects. In particular, immunological reactions occur in responders, such as chills, sore throat, neck and limb pains, elevated temperature, headaches, gastrointestinal symptoms. These immune reactions are also an indicator that the patient is a responder. But as soon as the body has adapted to the dose increase, those symptoms disappear again.

Alternative to Viread:

A good alternative to Viread is the proprietary drug **Vemlidy** (TAF = Tenofovir alafenamid), which has a much better side effect profile, although it is supposed to be equally as potent as Viread. Vemlidy can be taken at its full dose straightaway. It is possible to start out with a smaller dose, too, but it is better to reach full dosage soon to prevent the development of resistance. This is because it contains far less Tenofovir than Viread.

Because of its better tolerability, especially with regard to kidney function and bone density, Vemlidy is probably also better suited for older patients. The only catch on Vemlidy - besides the fact that, unlike Viread, it is not yet available as a generic drug - is that it is still relatively new on the market, studies on which integrase inhibitors it can be combined with are still missing and only very few ME patients have had experience with it so far. The interaction between Vemlidy and, for example, the integrase inhibitor Raltegravir, which, as mentioned at the beginning, has to be added at some point, has not yet been investigated, but none is expected.

2. Additional phytotherapeutic treatments

The other pillar of my treatment concept is the additional administration of **antiretrovirally active phytotherapeutics**. This has enabled us to successfully prevent the use of a synthetic integrase inhibitor such as Raltegravir and also avoid protease inhibitors required in regular anti-HIV combination therapy. This not only saves a lot of money, but also a range of possible side effects and long-term damage. Furthermore, the risk of resistance development with these phytotherapeutic agents is relatively low.

First and foremost **Cistus Incanus**. Cistus shows broad antiviral activity in vitro with a low risk of virus resistance. It is in a way effective as an entry inhibitor in HIV (Rebensburg et al. 2016) and contains several anti-HIV components.

Katharina Voss, Copyright 2018 (Author of a German textbook on ME entitled
"ME - Myalgische Enzephalomyelitis vs. Chronic Fatigue Syndrom: Fakten Hintergründe Forschung", tredition 2017)

It works at the entry level already, which means that treatment with Cistus blocks the entrance of the virus into the host cell at a very early stage and prevents the docking of virus particles onto cells. This effect provides maximum protection of host cells against virus attack. Many other, synthetic entry inhibitors - according to the study - only take effect at a later stage of the entrance procedure. Cistus, however, already acts as a so-called attachment inhibitor, similar to Pelargonium sidoides, a medicinal plant from South Africa. (Helfer et al. 2014) Cistus is also said to have an advantage over synthetic integrase inhibitors, as it is effective against more HIV genotypes than, for example, Raltegravir. (Cf. also e.g. Depatureaux et al. 2015)

On the side, Cistus also effectively fights upper respiratory tract infections, possesses antibacterial, antiviral and antifungal properties and thus also attacks the so numerous but mostly occult infections present in ME patients. It has also shown in vitro growth-inhibiting activity against Borrelia, with which ME patients are often co-infected.

In our case, a total of 2100mg of Cistus in capsule form distributed throughout the day has proven to be an effective dose. It is imperative that Cistus be taken with a time gap of at least two hours between it and Viread/Vemlidy. According to our experience, it is probably a good idea to start with Cistus before beginning ART, so that co-infections can be treated in advance. Moreover, this way the organism does not have to get used to two new drugs at the same time. Cistus incanus is available in capsules and lozenges, for example, the latter can also be used for immunological reactions such as sore throat or fungal infections in the mouth and throat. With all the intolerances that are so common in ME patients, it is probably better to start treatment with Cistus slowly, too and then gradually increase the dose.

Reishi (Ganoderma lucidum), recommended to us by Dr. Mikovits, strengthens and activates the immune system and has a number of other interesting properties, especially for ME patients, because Reishi also inhibits EBV activation. In addition, according to my literature research, it is effective against HIV-1 and inhibits HIV-1 protease. That is why we use it as a protease inhibitor; one capsule (500mg) per day.

In addition, one can take green tea capsules. Some **green tea plant extracts** have, according to my research, an inhibitory effect on the activity of the Rauscher mouse leukemia virus, which is related to HGRV in some ways, and also on HIV reverse transcriptase. Green tea contains epigallocatechin-3 gallate, a powerful antioxidant, which thereby also inhibits the replication of HI viruses and could thus potentially be used as an additional therapy for HIV-1 infection. According to Dr. Mikovits, in a way it draws retroviruses from the tissue. We take one 250mg green tea capsule daily.

Whether our successful, to my knowledge until now unique experiment with a synthetic reverse transcriptase inhibitor in combination with phytotherapeutic entry, protease and reverse transcriptase inhibitors (unique at least with regard to the - high-dose - use of Cistus Incanus as entry inhibitor and which I consider the most important and effective additional treatment) is applicable to other patients will only become apparent over the course of time. If this does not work for others, chemical integrase inhibitor Raltegravir would most likely have to be added after some time, usually at the latest after one year, namely when progress stagnates or even decline sets in again.

Katharina Voss, Copyright 2018 (Author of a German textbook on ME entitled
"ME - Myalgische Enzephalomyelitis vs. Chronic Fatigue Syndrom: Fakten Hintergründe Forschung", tredition 2017)

Since the research team of the internationally renowned Helmholtz Association of German Research Centres in Munich, which discovered the infection-blocking effect of Cistus against the HI retrovirus, assumes that the antiviral activity of Cistus incanus will allow for a dose reduction in anti-HIV combination therapies and thus to curb side effects and toxicity risk, it does not seem so far-fetched if I postulate the same infection blocking effect of Cistus against HGRV, which may cause the ME disease. The Helmholtz scientists have, by the way, already filed a world patent application.

Raltegravir:

Raltegravir is so far the chemical integrase inhibitor of choice for ME patients. As long as the patient continues to make progress, however, experience to date suggests that it is not necessary to take it. Only when no more progress is being achieved would Raltegravir have to be added.

With regard to the dosage of Raltegravir for ME, there are only testimonials from patients, which I can solely reproduce here, as we ourselves - thanks to Cistus Incanus - have not yet gathered any experience with the drug. Raltegravir is described by patients who take it as a very strong drug. It might therefore be advisable to start out with a lower dosage, e.g. half the original dose as well. That would be 200mg in the morning and 200mg in the evening. By the time a patient starts treatment with Raltegravir, one should already be doing reasonably well overall, not least because of possible side effects.

Mitochondria:

Most often mitochondrial function is being doctored with all possible means in ME patients - not seldom with the result that the patient is subsequently even worse off. But what if strengthening of the mitochondria leads to cells infected with a possible retrovirus also being strengthened and thus able to multiply even faster?

Therefore, it is in my opinion important to first of all gain control over the possible retrovirus and all other, mostly occult viruses and bacterial infections. By the way, mitochondrial function, which is reduced by disease, repairs all by itself through ART - at least this is our experience.

That is why strengthening the mitochondrial function while taking synthetic ARV is primarily about buffering potentially harmful effects of the drugs. Time-displaced to Viread/Vemlidy intake, **N-acetylcysteine** (NAC, caution in case of histamine intolerance!), **glutathione** or **niacinamide** (vitamin B3 flush-free) is suitable for this purpose.

Actually, it has been proven in vitro that NAC and glutathione also suppress the replication of HIV-1 and are therefore antiretrovirally active in addition to their mitochdria-strengthening properties. Especially in HIV patients with advanced immunodeficiency, a short-term, high-dose combination treatment with NAC and vitamin C seems to be of therapeutic value. Glutathione deficiency is also common in HIV-infected individuals and therefore administration of NAC seems to be a useful supplementary therapy, not only to increase protection against oxidative stress and improve immune system functionality, but also to promote the detoxification of drugs.

Katharina Voss, Copyright 2018 (Author of a German textbook on ME entitled
"ME - Myalgische Enzephalomyelitis vs. Chronic Fatigue Syndrom: Fakten Hintergründe Forschung", tredition 2017)

Treatment with NAC could therefore also be useful for other diseases in which glutathione deficiency or oxidative stress plays a role (such as ME!) - according to the results of a study on HIV.

Niacinamide (vitamin B3), especially nicotinamide riboside, has proven to be a promising treatment strategy for mitochondrial myopathy in animal models. It has beneficial effects on energy metabolism and neuroprotection.

But what could be even more crucial: Niacinamide seems to be effective against multi-resistant germs, which even healthy people, but especially ME patients, are often abundantly populated with. A population which a healthy person can usually cope with well could possibly have a devastating effect on weakened ME patients combined with viral loads. With niacinamide flush-free 500mg daily, a dose still below the tolerable upper intake level set by the European Food Safety Authority, a low-cost option for controlling these hospital germs is available.

General remarks:

Good vitamin and mineral supplementation during antiretroviral therapy is also important, the usual things to take with ME. Before doing blood tests, various dietary supplements should be discontinued in order not to falsify results. The intake of dietary supplements should always be time-displaced with respect to ARVs. Attention must also be paid to any interactions and whether contraindications are present. Milk thistle (silybum marianum) for liver detoxification is - if tolerated - certainly not wrong either. Besides, patients undergoing treatment with ARV should drink plenty, ideally water, and eat as healthy a diet as possible. Often this is not feasible at the beginning of ART for many ME patients because of the numerous food intolerances present, but those disappear - just like fragrance intolerances - under therapy by themselves - thus our experience at least.

Outlooks:

Based on the few experiences available so far worldwide, it must be assumed that ART will be a permanent medication. This is also supported by our experiences to date. So there is no talk of a cure, just as little as for HIV patients who are treated with ART. In the case of successful ART, however, even as an ME patient one can expect to be able to lead a reasonably, ideally even quite normal life - at least as long as one tolerates the strong drugs well and does not suffer from too pronounced persistent side effects.

Abortion of therapy can lead to a relatively rapid return of the full-blown clinical picture of the disease. Attempts to establish a two-day break every week in order to keep the toxicity risk as low as possible were not effective in our case because a significant deterioration of the condition would occur at the latest on the second day and symptoms would flare up again.

Even with very successful ART, a few but not always restrictive symptoms can persist for quite a while. Whether a completely symptom-free life under ART is possible, we are not yet able to say at this time.

During recovery, mood swings and a temporary increase in irritability, i.e. a certain overall mood instability, may become apparent. The same has been reported from those recovering from previous epidemics. (Cf. Lancet 1956) Interestingly, these symptoms do not occur at all or only very rarely in many severely ill patients during the illness. Whether they are pathologically caused or only come to light through the attainment of full consciousness about the extent of losses suffered due to disease, which the severely ill cannot fully realize, has not yet been researched.

Another hurdle during gradual regeneration is the difficulty of regaining confidence in one's own body. If one has for many years made the experience that any form of stress leads to a deterioration in the condition, adapting is not always easy. But over time, confidence returns, namely when one has often enough experienced that one no longer has to "pay" for physical, mental and emotional efforts with Post-Exertional Neuroimmune Exhaustion (PENE).

But one thing you should know before deciding on ART: ARVs aren't candy! We therefore hope that in the not too distant future there will be treatment options that will make the use of synthetic ARVs obsolete. And I already have an idea...

This blog entry is dedicated to Dr. Judy Mikovits.

Katharina Voss, Copyright 2018

Disclaimer
Reading this blog is no substitute for professional medical advice. It does not replace a visit to the doctor. This blog is not for diagnostic purposes. If you suspect that you have Myalgic Encephalomyelitis or "Chronic Fatigue Syndrome", please consult a doctor. The author is not a medical professional. The author is not responsible for any damage or claims that may arise from reading this blog. This blog is for information purposes only. It is intended to provide information to present the disease in as many aspects as possible and to provide and discuss international research results on Myalgic Encephalomyelitis and Chronic Fatigue Syndrome. The author reserves the right not to be responsible for the topicality, correctness, completeness or quality of the information provided. Liability claims against the author relating to material or immaterial damage caused by the use or non-use of the information provided or by the use of incorrect or incomplete information are generally excluded. No responsibility is taken for the contents of linked pages, including all sub-pages, as no influence can be exerted on their design and contents. This declaration applies to all links in this blog and to all contents of those pages to which links lead. The author hereby explicitly declares that at the time these links were created, no illegal content was discernible on the linked pages. The author has no influence on the current and future design, content or authorship of linked pages. Therefore, the author hereby explicitly distances herself from all contents of all linked pages that were changed after the link was placed. This statement applies to all links and references set in the blog.

translated with deepl.com by ys