An Old Therapy Returns With A Bang

Over thirty years ago I first used daily injectable Kutapressin, a porcine liver extract, on a CFS patient who was both quite young (age 16) and had been bedridden for two years after a mono-like illness at age 14 in HS. Before his collapse, he was the captain of his soccer team and a straight A student at a Charlotte High School in the late 1980's.

His parents were distraught as he could barely get out of bed for the previous two years before I first saw him. At this time, I was aware of three facts about Kutapressin. 1) It had been used since the 1930's by dermatologists to treat shingles (a re-activated herpes virus) and in the 1920's to treat severe acne vulgaris. 2) A prospective study by a physician in Houston, TX on 30 odd CFS cases using daily injections of kutapressin for six months showed slow but steady improvement by patient self-assessment scores. 3) Dharam Ablashi, the co-discoverer of HHV-6 at the NIH, showed that kutapessin was a strong inhibitor of HHV-6 in vitro which was much on my mind as a causative agent in cases like this 16 year old.

Studies is the 1950's and 1960's showed that kutapressin regulates bradykinin which is an inflammatory mediator not unlike histamine. However, kutapressin appears to be a net anti-inflammatory in the skin so exactly how it interacts with bradykinin is not fully understood nor are its apparent anti-viral effects. More recent studies on kutapressin suggest that its actions are far more complex deep within cells. Just as my Cell Signaling Factors are complex and possibly acting via G-protein coupled receptors (GPCR's), the actual deeper mechanisms of kutapressin are unknown. It is considered a nutritional supplement but if injected, is regulated by the FDA. Kutapressin was grandfathered in by the FDA as safe and effective for inflammatory skin disorders.

Returning to the 16 year old, I started him on kutapressin at 1 cc SQ and within a year, he was out of bed and in two years he had started college part-time and in three years, he was a full time college student. He had learned to vary his kutapressin injections from 1-4 injections per day depending on how he felt. Briefly, I halted the injections thinking that perhaps he had just gotten better by chance alone but he promptly relapsed so I placed him back on kutapressin. He would graduate from college and went on to medical school on daily kutapressin and eventually became a radiologist. He dropped by my offices one day while in radiology training and thanked me for giving him his life back and he was never going to stop kutapressin.

I have never been able to repeat that success but it is really hard to get CFS patients to self-inject daily for six months without seeing a short term benefit and short term benefits were not my expectations but I was wrong. Dose also matters and I did not appreciate that fact for the next 30 years.

The rights to kutapressin would eventually be sold in 2004 by Schwartz Pharma to Nexco Pharma Inc, in Houston TX, and rebranded as Nexavir and marketed as an anti-inflammatory/anti-viral, hence the name Nexavir (-vir is used for anti-virals). The FDA would step in, I assume due to the re-branding, and for a time, Nexavir largely disappeared from the marketplace and it went out of sight and mind only to return with a simple e-mail from the owner of Nexco Phama who simply asked if I had heard of the recent Nobel Prize in Medicine awarded to three scientists who had elucidated how cells sense and respond to oxygen or the lack of it. He had recalled my studies on the aberrant response in CFS cases to low dose oxygen.

I returned the e-mail and we struck up an e-mail conversation and I learned that Nexavir was available in both injectable form and a new and better skin paste. I was given a special price to start Nexavir at high dose in a very sick 21-year old bed-ridden with CFS since age 18. I have mentioned her before as I tried Ketamine on her last year which helped her POTS but over time, not her CFS.

Three weeks ago, I started this 21-year-old on 1 cc SQ BID of the injectable Nexavir by insulin syringe and 3-pumps of the skin paste daily for a total daily dose of ~110 mg of Nexavir. This is a high dose and on a retail basis is expensive. The response was immediate and over time (3 weeks) produced a notable change in this very disabled case. She is up and around and considering what to do with her life now that it seems to be retuning, slowly but surely, which I saw 30 years ago in a similar case. Interestingly, she notices an increase in energy within minutes of the injection but not the paste. In addition, she sees a bigger response if she gives both 1 cc injections, one after the other. It appears that dose matters, especially in sicker patients and this is very important to note.

Yesterday, I saw a long-time patient from Los Angeles at her annual visit with echocardiography which I typically do annually at a sonography facility in Morganton, NC.

The echocardiogram is very revealing regarding cardiac energetics and can measure an important proxy for severity of illness, namely, the cardiac output normalized to body size called the cardiac index (in this case the body surface area in sq meters). Normal cardiac index for a healthy adult is 3.0 - 4.0. CFS cases average about 2.4 on 2-D echo and about 1.7 on 3-D echo which is more accurate. The sicker the patient, the lower the cardiac index as it correlates with over all energy capacity or demand in the body as a whole as well as with disability status as established by Peckerman et al, 2003 in a landmark paper on this issue in CFS. Low cardiac output is an established objective measure of disability in SSI litigation and is now established in case law before administrative law judges in disability matters. I have used it to establish disability in medical legal-matters as a basis for my opinion on disability for over a decade and have never lost a case.

I can also measure the IVRT (IsoVolumetric Relaxation Time) in msec which is an indirect and inverse measure of cardiac energetics in real time and over time (minutes) after I apply any treatment on the echo table (SL or transdermal or inhalation or oral or SQ/IM). IVRT is the time in msec between aortic closure and mitral opening. It is not a trivial measurement to make reproducibly but I have established a technique to do just that using repeated, triplicate measures. An expert sonographer can do this well and reproducibly after about 10 minutes of instruction.

Yesterday, my sonographer measured the IVRT at baseline in my LA patient at 90 msec (normal is < 85 msec if over 40-years old). Two minutes after applying 3 pumps of Nexavir cream, her IVRT dropped to 65 msec and then slowly returned to 90 msec over about 8 minutes. This means that Nexavir cream at 60 mg caused a 28% "increase" in cardiac energetics and partially explains why the 21 year-old feels better in minutes after a large injection. The patient, age 59, was unaware of this cardiac transformation which occurred in minutes and admittedly it was transient but what I have observed over the last 12 years is that a positive IVRT response (IVRT decline) typically predicts a good clinical response over time if the patient persists with that treatment.

A 28% positive response is the largest positive response on echo I have ever seen and it is intriguing as the known established effects of nexavir as an anti-inflammatory / anti-viral do not explain a rapid 28% cardiac energetics improvement in 2 minutes.

If patients are interested in a 30-day trial of Nexavir, I can get it substantially discounted for my patients directly from the manufacturer. Please arrange a PC if interested so I can go over dose and injection technique and on-going strategies if Nexavir works within that 30 days. Recall that neuro-inflammation is a key and perhaps defining element in CFS and Nexavir is a potent anti-inflammatory and used in human medicine as such for almost 100 years. However, dose matters and Nexavir is not inexpensive but over time, costs can be restrained by steady dose reduction.

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