Looking for a Biophysical Approach to Early Stages of Chronic Kidney Disease

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Abstract— Chronic Kidney Disease (CKD) and its subsequent complications and consequences are an increasing concern in general population. A biophysical integrated approach in early stages of CKD was investigated in 30 patients with a 12-month follow-up. A clinical approach based on the use of an electro medical device (Medselect 729) was employed following previous reports as well as the procedure of electromagnetic information transfer through aqueous systems. Interestingly, we observed a significant increase in the estimated glomerular filtration rate (e GFR) according to CKD-EPI formula (+11.57 ml/min; +18.43%, $p < 0.0001$). Beside further studies are certainly recommended, a biophysical integrated approach in the management of early stages of Chronic Kidney Disease seems actually to be feasible, effective, and promising.

1. INTRODUCTION

Chronic Kidney Disease (CKD) and its subsequent complications and consequences are an increasing concern in general population. Moreover, CKD is very likely related to aging. CKD contributes also to the general increase of allostatic load, as consequence of adaptive stress [1], and frailty in elderly people [2]. According to the allostatic load theory, CKD is a result of the increasing rate of chronic stress-related syndromes in both young and elderly people [3]. Successful management of CKD may play an important role on successful aging strategies together with the management of other emerging chronic diseases.

Biophysical methods are emerging tools in clinical practice and several studies have shown their potential use in preventing chemotherapy induced mielotoxicity [4], in treatment of gonarthrosis [5], and rheumatoid arthritis [6], in improvement of renal function in a case of autoimmune nephritic syndrome [7], in relieving from chronic constipation or diarrhoea [8], and as an effective alternative to pharmacological treatments of chronic pain [9–11]. Biophysical therapies are thought to be effective due to a resonance effect [12]. Resonance occurs between therapeutically delivered signals and target tissues, which allows the achievement of local and/or systemic effects [13]. In this pilot study, we integrated the current CKD treatment of early stages of CKD with a biophysical procedure to assess whether it could be of some support.

2. MATERIAL AND METHODS

2.1. Study Design

This was an open-label prospective cohort study.

2.2. Study Population

30 patients aged 63.60±11.83 (13 Males, age 61.92±12.69 and 17 Females, age 64.88±11.35), with early stages of CKD (CKD stages I and II, estimated Glomerular Filtration Rate, eGFR > 60 ml/min) were enrolled. After being informed about the aim, methods, and timing of the study, all patients provided a signed written informed consent form. This study was performed in accordance with the declaration of Helsinki.

2.3. Evaluation of Estimated Glomerular Filtration Rate

After considering which method should be simple, useful, and reliable among those available in clinical use for estimation of the glomerular filtration rate [14] we decide to employ the CKD-EPI formula [15]. Serum creatinine was sampled every three months in order to calculate CKDEPI values before each administration of the biophysical procedure.

2.4. Biophysical therapy procedure

A 2-step treatment was administered to each patient. The 1st step consisted of selecting the program "regulation therapy" on the touch screen of the Med Select 729 device (Wegamed, GmbH, Essen, Germany) to record the endogenous input signals at the low back region of each patient and of delivering the therapeutic electromagnetic output signals on an electromagnetic, full body, carpet on which the patient laid on for 10 minutes. The program "basic drainage therapy" was next selected from the touch screen of the Med Select 729 device to record the endogenous input signals at the renal region and deliver the therapeutic output signals at the kidney's site for 10 minutes. These output therapeutic signals were meanwhile recorded on a commercial available aqueous system (Nomabit Base, Named SRL, MB Italy) by placing the solution into a special output coil, built-in for this aim in the Med Select 729 device. This medical device operates in the low frequency range (between 0 and 20 KHz) using a magnetic field with an intensity similar to the Earth's magnetic field with a maximum of 50 µT. It allows to record input signals using two electrodes and to send output signals to the patient through two magnetic electrodes for local use, for example, on the pain site, or through a magnetic carpet where the patient can lay down (in this way the entire body of the patient can be treated). Therefore, the device can simultaneously deliver a local and systemic treatment. The recording circuit and procedures are described in detail in a previous study as Electromagnetic Information Transfer Through Aqueous System [16] . The Nomabit Base aqueous solution was subsequently self-administered by the patient in order to allow the therapeutic information recorded to be delivered according to a weekly plan beginning on Monday with a single drop and increasing by one drop/day up to 6 drops on Saturday; no therapy was administered on Sunday [7, 9–11]. The Nomabit Base solution is composed of oligominerals and is currently used as a food supplement. It is provided with a dropper and stored in an aluminum-shielded container, which ensures that the signals are preserved on the aqueous solution and are protected from environmental thermal and electromagnetic pollution. This is an "off label" use of a common dietary supplement, which is already suited to be stored for a long period of time (up to three months after opening, as indicated by the manufacturer, which avoids the risk of alteration of its characteristics).

2.5. Statistical Analysis

Statistics was performed with Student's t-test. A p-value < 0.05 was considered statistically significant.

3. RESULTS

All patients who enrolled completed the study. No side effects were reported. At baseline, mean eGFR, according to the CKD-EPI formula, was 67.80±12.75 ml/min. After 12 months, mean eGFR score was 79.37±14.71 ml/min. There was a 18.43% increase in eGFR ($p < 0.01$) (Figure 1).

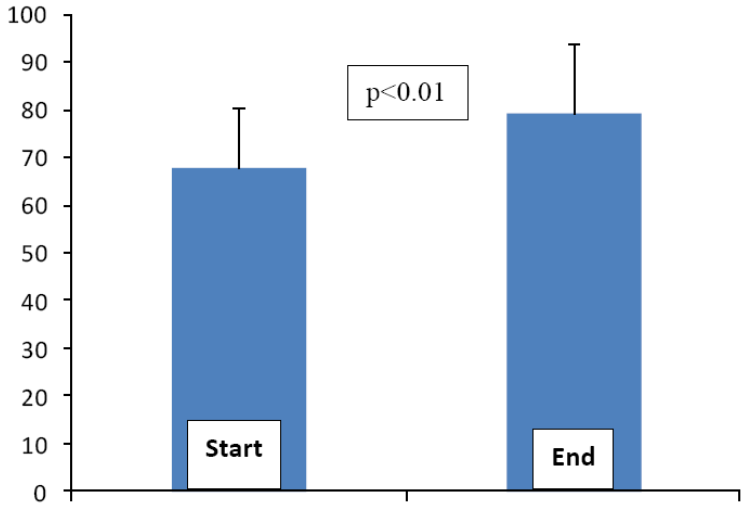

Figure 1: Variation in the estimated Glomerurar Filtration Rate eGFR (on the left column) from the start to the end of the study after 1 year.

4. DISCUSSION

The aim of this pilot study was to identify a novel potential synergistic strategy for early stages CKD patients. The use of the electromagnetic information transfer of endogenously produced therapeutic signals seems to represents a very promising therapeutic tool since only a single treatment needs to be performed by the physician on each patient every three months. A total of four treatment were therefore delivered during the study. This approach may represent a novel approach to improve quality of life for patients and save clinical resources. A significant increase of eGFR has been observed, with no side effects. This preliminary study provides substantial evidence that a biophysical approach to early stages CKD patients is feasible, effective, safe, and long lasting. Since, CKD is progressively increasing in general population [17], in adults [18], and especially in elderly [19], these results may contribute to delay the progression of CKD. eGFR reduction associates with all-cause mortality and cardiovascular even in a low risk population [20]. Therefore, any synergistic strategy aimed to manage effectively early stage CKD patients, through maintenance or increase eGFR should be considered as a complementary and useful tool to manage public health and to support successful aging [21, 22].

5. CONCLUSIONS

In conclusion, the integration of a biophysical approach in current management of early stages of CKD appears to be feasible, safe, and effective. A biophysical integrated approach may also represent a synergistic and personalized tool to reduce age-related global functional decline [21, 22]. Beside further studies are certainly recommended, a biophysical integrated approach in the management of early stages of Chronic Kidney Disease could probably represent a valuable integrative tool in the field of preventive medicine.

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