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INFLUENCE OF JUNFENG BFS WATER ON MICROCIRCULATION – A CLINICAL STUDY BY NON-INVASIVE MEASUREMENTS OF THE HUMAN EYE

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ABSTRACT

Background: Junfeng BFS Water (JBW) is normal drinking water modified by means of a certain electromagnetic field. Animal studies have shown that drinking of JBW has a positive impact on microcirculation in different organ systems.

Patients and Methods: A randomized placebo-controlled double blind study was performed to examine the influence of JBW on microcirculation of the eye, functional outcome and subjective well-being. 60 patients / participants (age between 45 and 85 years) with normal eyes, chronic open angle glaucoma or dry age related macular degeneration had to drink 2 liters of JBW (JBW+) respectively normal drinking water (placebo group = JBW-) per day over a period of 2 months.

Eye examinations have been performed in both eyes at day 0, day 30 and day 60: best corrected distance visual acuity (logmar); OCT measurements of central and average retina thickness, retinal nerve fiber layer thickness; optical nerve head rim surface and volume, optical nerve head cup/disc ratio; tonometry and ocular pulse amplitude with Ziemer Pascal contour tonometer.

Statistical analysis was performed using the IBM SPSS program. Bivariate statistics were performed using the ANOVA-test. The level of significance was a=0.05.

Results: Ocular Pulse Amplitude (OPA) which is a direct parameter for ocular blood flow was highly significantly increased (t-test) in all 3 populations (normal eyes, glaucoma, macular degeneration) as well in the overall population of JBW+ compared to JBW- after 1 month and after 2 months.

Visual acuity, Tonometry and all OCT parameters did not show any statistically significant difference (a > 0.05 in ANOVA-test).

Conclusion: Our results seem to confirm former findings that drinking of JBW has a positive influence on microcirculation since we found a significantly increased Ocular Pulse Amplitude in a population drinking JBW compared to a placebo drinking control group. If these results can be confirmed by further studies and in larger populations this could mean in ophthalmology that diseases with a reduced microcirculation as for example Normal Tension Glaucoma can be positively influenced by the drinking of JBW.

KEYWORDS : Junfeng BFS Water – Microcirculation – Eye Examinations – Ocular Blood Flow

Background

Junfeng BFS Water (JBW) is normal drinking water treated by Junfeng BFS Water treatment and Healthcare Device. Optimization of water is achieved by generation of an electromagnetic field with certain electromagnetic oscillations. The physicochemical properties of water are changed, such as the smaller water clusters, the decreased content of chloroform and the increased solubility.

According to the producer of the device, the Guangdong Junfeng BFS Technology Co., Guangzhou, PR China, JBW these changes will lead to an improvement of conductivity of the water getting closer to the spectrum of human plasma conductivity; to an improvement of permittivity which will be increased; to an increase of dissolved oxygen. JBW is supposed to be easier be combined with body fluids, to get better involved in metabolism and to exert biological effects.

Animal studies that have been commissioned by the producer of the device show that JBW has indeed certain biological effects as improvement of microcirculation and the functions of blood rheology properties. Furthermore, an improvement of immune function was observed as well as beneficial aspects to intestinal digestion and absorption and an antioxidant function.

Since the human eye can be regarded as a Biomarker of the Cardiovascular System and since the eye can be easily examined by non-invasive measurements this organ was chosen for a clinical study.

Aim of our study was to see if drinking of JBW improves microcirculation of the eye and if it has further benefits on the physiology of the eye and visual function.

Patients and Methods

General Remarks:

This study is following Good Clinical Practice according to the 'Declaration of Helsinki' and was approved by the Ethical Commission of the Kanton Zürich, Switzerland (KEK-ZH-Nr. 2016.01190).

The study has been registered by the World Health Organization WHO via German Register for Clinical Studies DRKS (DRKS-Nr. 00010554).

We performed a randomized placebo-controlled double blind study; that means that neither the patient nor the doctor or his assistant knew if they received a working device (JBW+) or a non-working device that had no influence on normal drinking water (JBW-). Randomized delivery to the patients was performed according to a preexisting list with numbers of the devices. According to this list we age-matched couples of 2 patients with always one JBW+ and one JBW- were formed.

All patients had to drink 2 liters of JBW+ respectively JBW- per day over a period of 60 days. The patients had to fill out a drinking protocol about the amount of water per day and about eventual side effects.

Patients:

20 patients suffered from Primary Open Angle Glaucoma, 20 patients had Dry Age-Related Macular Degeneration, 20 patients with normal eyes were involved. 10 patients of each subgroup were JBW+, 10 JBW -.

Patients with an age range from 45 to 85 years got involved during December 2016 und May 2017. 59 patients came from private eye clinic PD Dr. Dieter Eisenmann, Chur, Switzerland, 2 patients were transferred from private eye clinic Dr. Giovanni Spina, Chur, Switzerland. 1 patient had to be excluded from the study.

Male and female at random without quota requirement.

The following exclusion criteria were respected:

- Psychological impairment
- Dementia
- Chronic diarrhea
- Lethal diseases
- Cancer / Tumors
- Very athletic patients

- unusual high number of different medications

The following diseases could be included or were even welcomed:
- Diabetes
- High blood pressure
- Coronary / Vascular problems
- Sjögrens-Syndorme
- Rheumatic arthritis

Methods:
All Eye Examinations were performed at day 0, day 30 and day 60:

- Best corrected distance visual acuity: 5m-distance, results were analyzed in logarithmic values (logmar)
- Optical Coherence Tomography (OCT): a non-invasive imaging test that uses light waves to take cross-section pictures of the retina and the optic nerve head that allow a mapping and a measurement of the thickness.

The following parameters were taken using a Optopol Copernicus™ a high definition OCT of the latest generation using Spectral-

Domain technology:
- Central and Average Retina Thickness
- Retinal Nerve Fiber Layer Thickness
- Surface and Volume of Optical Nerve Head Rim
- Optical Nerve Head Cup/Disc-Ratio

- Ziemer Pascal™ Dynamic Contour Tonometer: a tonometer that measures intraocular pressure (IOP) 100 times per second. From these measurements, ocular pulse amplitude (OPA) is derived which is the average difference between diastolic and systolic IOP. OPA is reflective of the relative quality of the ocular blood flow.
- Intraocular Pressure (IOP): according to many studies the most accurate and precise tonometer that is measuring independently from the patient's cornea
- Ocular Pulse Amplitude (OPA): a parameter for ocular blood flow

Statistical Analysis:
The IBM Statistical Package for the Social Sciences (SPSS; latest version 2015) was used for descriptive and bivariate statistics. The ANOVA-test was used for analysis of statistical significance. The level of significance was a = 0.05.

All statistics were done at the Institute for Statistics of Otto-von-Guericke University, D-Magdeburg under supervision of Hagen Thieme, MD PHD, Director of the University Eye Clinic, D-Magdeburg.

All data were imported into SPSS and analyzed by an independent scientific assistance who was not informed about aims of the study, groups and subgroups of the patients.

Results
General: An overall of 61 patients was enrolled in the study.

One patient (JBW- Glaucoma) stopped the study after 10 days because he was not able to drink 2 liters per day. He was excluded from the study and another one got enrolled at his place.

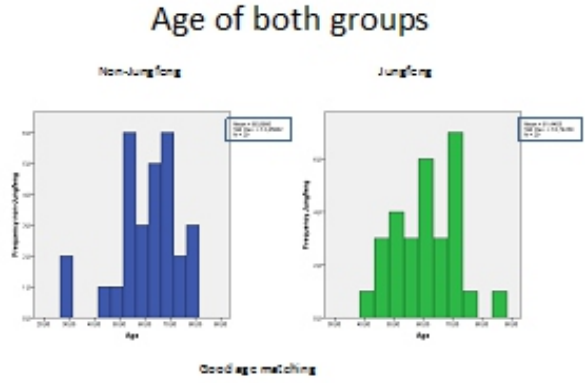
2 patients (1 JBW+ AMD, 1 JBW- Glaucoma) stopped the study after 39 respectively after 44 days; the first for appearance of slight edema of the legs; the 2nd for inability to continue drinking 2 liters per day. Both were left in the study since they had completed day 0 and day 30 correctly.

3 patients (2 JBW + AMD, 1 JBW - Glaucoma) did not have complete OCT results for problems of fixation with one eye. They were both left in the study since because they gained 28 of 36, 24 of 36 respectively 28 of 36 OCT parameters.

Age distribution of both groups is shown in table 1.

Distribution of both groups is pretty homogeny with proves that the study design with age matched pairs for both groups was effective.

Table 1

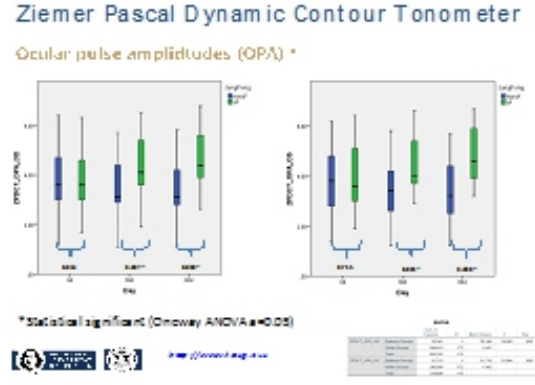


Ocular Blood Flow:

OPA measured by Pascal Tonometry as an indicator for ocular blood flow and microcirculation of the eye was highly significantly improved in the JBW+ group compared to JBW – (Table 2). This result was found in all 3 subgroups.Oneway ANOVA analysis shows a level of significance for both eyes of a > 0.01 at day 30 and day 60.

Male and female gender of JBW+ performed better on both follow-ups compared to their corresponding gender in JBW-

Table 2



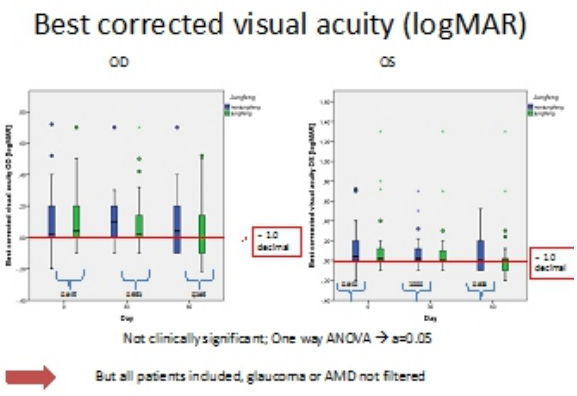
Pascal Tonometry:
Intraocular Pressure measured by Pascal Dynamic Contour Tonometry did not show any significant differences between all JBW+ and JBW- groups in Oneway ANOVA analysis at both follow-up dates.

There were no statistically significant differences in the 3 medical subgroups or in gender subgroups.

Visual Acuity:
Best corrected visual acuity was measured at 5 m distance and values were expressed in logmar.

SPSS / ANOVA analysis did not show any significant difference neither in the overall populations of JBW+ and JBW- (table 3) nor in the subgroups.

Table 3



OCT Examinations:

All OCT measurements of central retina and optic nerve head did not show and significant differences between JBW+ and JBW- in the overall populations as well as in the subgroups (Oneway ANOVA-test).

Discussion

Study Design and Statistics:

It was our aim to perform a clinical study according to the standards of a Swiss Ethical Commission to find out if drinking of JBW has any positive influence on the physiology or function of the human eye. Since former studies had shown an improvement of microcirculation in animals we put emphasis on examinations of parameters that could confirm these results.

The study was performed as a randomized double blind study which fulfills the criteria of neutrality, safety and objectivity.

The statistical analysis by the IBM SPSS program includes the fact that al data has to be imported by a neutral person which is not informed about the aims of the study, the composition of the population or on subgroups.

The analysis by the software package itself cannot be influenced from outside.

So, results cannot be manipulated during the examination process or during analysis.

These are standard criteria for a later possible publication of results in serious scientific media.

The Human Eye as a Biomarker of the Cardiovascular System:

The human eye can be regarded as a window to heart and the cardiovascular system (1). Many cardiovascular diseases or their risk factors can be found in the eye (e.g. occlusion of blood vessels, hypertension, arteriosclerosis, diabetes). On the other hand, several eye diseases are based on vascular disturbances or dysregulations of microvascularisation (e.g. disturbed autoregulation of ocular blood flow in hypotension; appearance of Normal Tension Glaucoma).

A major advantage of the eye as an organ is that it is easily accessible and microcirculation and other functional examinations can be performed by non-invasive methods. For this reason, the eye was chosen as organ of interest for our study.

For example, microcirculation parameters as ocular blood flow (OBF) can be measured non-invasively with the Pascal Dynamic Contour Tonometer by determination of the ocular pulse amplitude (OPA) which is the average difference between diastolic and systolic intraocular pressure (2).

Ocular blood flow:

In our study, Oneway ANOVA statistical analysis showed highly significant improvement of OBF by OPA measurement for JBW+ in comparison to JBW-. This after 1 month as well as after 2 months. We see this as a strong indicator that JBW seems to have the quality to improve microcirculation of different organs as it was shown in previous animal studies for the mesentery in rats (3).

An improvement of ocular blood flow could be of importance in microcirculation depending eye diseases in general. Glaucoma is recognized as a leading cause of blindness. It is estimated that 9.4 million people aged 40 years or older in China have glaucomatous neuropathy. Of this number 5.4 million (55%) are blind in at least one eye and 1.7 million (18.1%) are blind in both eyes (4).

An improvement of the microcirculation of the optic nerve could be extremely helpful in different types of glaucoma as Normal Tension Glaucoma (NTG). Since a decreased OPA is associated with functional and structural damage in open-angle glaucoma (5) an improvement of OPA as we noticed it in the JBW+ population could prevent such damages. If results are confirmed in a bigger population we see the potential for JBW as an additive for conventional medical treatment that consists traditionally in the application of eye drops to reduce IOP.

OCT measurements:

Age-related Macular Degeneration (AMD) and Primary Open Angle-Glaucoma (PAOG) are disease in whose etiology a disturbance of microcirculation seems to play a certain role. The progress of the diseases can be followed non-invasively by OCT measurements. In our study, preliminary statistics did not reveal any difference between the 2 populations. This may be due to the fact that both diseases generally are progressing very slowly and the time-interval of 2 months is too short to show any evidence.

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