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THE ROLE OF LASER IN DIABETES MANAGEMENT.

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Background and Objectives: Since 20 years and more some Authors report news and data about the hypoglycaemic effects of non surgical laser in diabetes type 1 and 2 (1,2,3,4). Different types of laser were used in association with other radiations, as magnetic field and electricity. Different procedures were followed. Few Authors published something on this topic, following the famous rules of the clinical research, as Helsinki. Declaration and other similar protocols. So these data were reported only as evidence based medicine. On the other hand, we can observe that diabetic mariners don't need hypoglycemic therapy when they are in high sea. Thus the large amount of light absorbed by these persons could have a therapeutic effect on the glucose metabolism. Perhaps this fact is caused by direct absorption of the sun reflexed by the water, with less portion of coherent light absorbed by the body.

At this moment, we know five different procedure of treatment of diabetes with light, associated with electromagnetic fields, and/or electrostimulation and/or laser rays(1,2,3,4). We still don't know what procedure is most effective, but we know that all these procedure influence the glycaemia positively. This effect is strictly dose-dependent, as all the other effects of non surgical laser and light on the biological tissue (5).

Aim of our study is to verify if some laser beam have effect on the glycaemia and on the management of the diabetes. We never interrupt the diet and the physical activity of the patients, because these always continue to have a primary role on diabetes management. We would like to verify the possibility to stop the esogenous insulin and the drugs in diabetes treatment

Study Design/Materials and Methods: We are testing a range of dosages that surely do not have negative effects on irradiated tissue, as reported in the literature (1-9). Previous experiments have demonstrated that laser irradiation (at a dosage level reported to be effective in the treatment of diabetic patients) can accelerate gastric emptying (1,2,3). This gastric emptying would result in an increase in the glucose blood level, if a patient eats within 4 hours before the laser irradiation. It is absolutely necessary that the patient fasts for four hours prior to the laser treatment. Fortunately, laser dosages planned for these treatments are well below the dosage necessary to cause local burns. Further systemic effects have not been convincingly demonstrated.

Potential adverse effects caused by hypoglycemia induced by the laser therapy can be treated with sugar absorbed under the tongue.

Any potential hyperglycemic complications can be treated with the prompt administration of insulin.

Each patient must be instructed to measure their blood glucose levels at the same hour each day. Usually diabetic patients know how to measures their blood glucose levels. Each patient must contact their physician immediately, if he/she notes any change in their daily health or functioning.

We started with an experimentation as phase 2 of the schema of the clinical experimentation.15 patients were enrolled in this experience, 5 with diabetes type 1 and

10 type 2., both sex and age 18-65 y.o. In details, we enrolled patients selected with the following inclusion and exclusion criteria:

a) Inclusion criteria:

- i. Type 1 2 human diabetes in compensative phase, both sex and middle-old age.
- ii. Weight normal or high.
- iii. Diabetes started more than one year ago

b) Exclusion criteria:

- i. Diabetes I II with unstable glycaemic control
- ii. History of hypo- hyperglycaemic coma
- iii. History of cardiovascular not treatable complication.
- iv. History of malignancy
- v. Previous participation in a clinical trial for hypoglycaemic drug effects control

c) Suspension criteria

- i. Patients with diabetes complication starting after laser treatment.
- ii. Patients who don't follow the protocol prescribed
- iii. Patients with adverse effects to laser irradiation (local burns, allergic reaction)
- iv.Patients who present some exclusion criteria that appear after the inclusion in the treatment protocol

Patients are informed about the investigative nature of the study and give their written informed consent prior to the treatment.

We used the same diode laser system (table 1) coupled with magnetic fields (15 Htz fixed) but different procedure of treatment. The Glycaemia was measured immediately before and 10 minutes after each session of treatment. Glycate haemoglobin were measured before and three months after the treatment. Insulin and anti-diabetic drugs were progressively reduced during the treatment, when the glycaemia decreased. In details, the patients with diabetes type 1 are irradiated in average once a day for 3 week, then once a week until the total normalization of the Glycaemia and of the other parameters. The patients with diabetes type 2 are irradiated in average once a week until the total normalization of the Glycaemia and of the other parameters. We control the glycosilate haemoglobin immediately before and three months after the start if the laser treatment, then each three months.

The glycaemia level is monitored first in the initial visit, then 10 minutes after treatment, the day after, at same hour after the irradiation, and each day, at same hour after the irradiation.

Patients in both groups stop taking insulin or hypoglycaemic drugs 4 hours before the laser treatment. They will resume taking the insulin only if the glycemic levels are not reduced by a minimum of 20% immediately after each laser treatment and persist for one day. Then the insulin and hypoglycaemic drugs are decreased progressively.

Results: Our first data are positive in both types of diabetic patients (tab 2 and 3). They stop the drugs therapy and the insulin therapy progressively, but they must continue to monitor the glycaemia once for day and more. The diet and physical activity continue to be very important. Follow up is excellent for both types of diabetes one month after the end of treatment, variable after six months, depending of the type of the diabetes and the behaviour of the patient after the treatment.

Unfortunately both types of diabetes patients require another cycle of Laser treatment one year after the first cycle.

Many hypothesis can be done about the action mechanisms of the light on the glucose metabolism: antinflammatory and regenerative effects on beta-cells and cromaphine cells, hyperaemic effect on the microcirculation, redistribution of the energy on the chakras, or all

these effects together (tab 4)

In conclusion, the fact is the normalizing effect of the laser treatment. on the glucose metabolism, after a cycle of 15 sessions of irradiation in average. The causes of that must be investigated. We need further studies for maintaining the positive results of laser treatment for longer time. On the other hand, we need to comparison between the different procedures light-based on diabetes treatment, for to decide the best procedure at the best dosage of treatment.

This experimental treatment must be approved by the ethical committees of each country. Curiosly this treatment was not approuved by Local ethic Committee of Firenze, Italy, but an Authority of that Committee suffering of diabetes type two required to be treated with laser and magnetic field! The mystery of the politic!

Our experimentation is conducted following the rules of the Good clinical practice established by the European Community, published on Italian Gazzetta Ufficiale, suppl n 191 18 August 1997, n. 39 18/6/2001, and the Helsinki Declaration.

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