EXPERIMENTAL HOMEOPATHIC RESEARCH ON "OPUNTIA FICUS INDICA"

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INTRODUCTION

The prickly pear, in the European imagining, is an iconographic symbol of the Mediterranean (Sicilian) culture.

According to what Fernandez De Oviedo reported (1535), the plant, native of the Mesoamerica (likely from Mexico), reached Spain with Colombo in 1515, as an ornamental species and fruit, and hence spread all over the Mediterranean area, discovering a more suitable habitat on dry or semidry land, which favoured its naturalization.

For its west Indian origin and morphological likeness to the Mediterranean fig, the new plant has been named "*Ficus indica*" (Linneaus and Miller). It belongs to the "*Opuntia*" type (from a prickly plant, not identified, described by Pliny the Elder in his "naturalis historia" among 170 types of "cactaceae").

Opuntia ficus assumes supreme importance in agronomica science for its several characteristics: its edible fruits, which can be taken fresh or dried, and are formed by big barrel-shaped berries, with thorny bristles spread all over the peel, and for the possibility to ferment it to extract alcohol (the seeds contain semi-drying oil) and for its flattened and fleshy branches used in animal and human food. (2,3)

The prickly pear tree ramification is characterized by multiple transformed stalks, great abundance of watery peel, laid out in disordered flat segments, named "cladophill": they contain mucilage, various oligoelements (such as calcium, potassium, phosphorus and a small quantity of sodium), vitamins (ascorbic acid, carotenoids, pantothenic acid) mainly used as forage, but also important in human nutrition and folk-medicine.

In the eighteenth century, navigators assumed it with salads preventing the scurvy, spreading the plant in most part of the world. Still today, in central America's food tradition, "appetizing" salads are prepared with the most tender cladophill of "nopal" (Mexican name) mixed with onions.

The virtues of the "tuna" (its caribeño name) were well known to the central America's population since the ancient times: in 1965 Callen found remains of cuticle in human faeces, dating back to over 7,000 years B.C., and "tuna" was also adored as a sacred plant by the Aztec, who named after it their imperial capital: "Tenochtitlan", near today's Mexico City, (teno from "tuna" – on a rock) (3).

The mucilage of the cladophill (like other cactaceae kinds) supply a soothing effect, haemostatic, decongesting, and moisturising which justifies its use in superficial wounds treatment, ulcers, infections and in the "boils maturation" and dermocosmesis. The farmers experience consideres it an effective remedy in hyperchylia, in peptic ulcer and against the colic pains (4,5,6). The high concentration of mineral salts (potassium particularly) explains its traditional use, as in Mexico, as a diuretic and cardiotonic remedy. (7,8,9,10,11)

The fibres, dried and pulverized are then prepared in pills that help the digestive processes and are used as a support to the obesity cure. If applied superficially it accelerates the heeling of wounds, reason why it is also known as the "heeling up tree".

Less frequently it is used to cure lung infections and facilitate childbirth. (12,13,14,15,16)

In the Mexican (and partly Sicilian) folk-remedy, cladophill is used in diabetes mellitus treatment.

Even though the important position occupied in the traditional use, the prickly pear has been ignored for a long time by the official medical science, attracting only recently the interest of the researchers.

Since the eighties, numerous studies lead and confirmed its gastroprotective and hypoglycemic activity, together with a positive influence on other metabolism disturbs as hyperuricemia and hyperlipemia.

The dehydrated pulp shows to have a great effect thanks to the high concentration of the polysaccharidic fraction formed by a polymer of various kind of sugar, as galactose and arabinose, known as "opuntiamannan", which binds the fat and sugar ingested, making them not absorbable and therefore expellable through faeces.

The acid pantothenic (vit. B3), helps the formation of coenzyme A and carries on lipidlowering affects. Both the cellulose and pectine, not digestible, work as an bulk-forming agent and create a fulling effect and an effective laxative.

The glycohemia is reduced 4-6 hours after administration, while, according to same authors, about the 34% of the cholesterol is lowered in a month (17,18,19,20).

All these qualities lead the culture association "The tree of life" of Catania, to carry out a homeopathic study monitored by Prof. Mario Matera, head of the Department of

Experimental and Clinical Pharmacology of the Faculty of Medicine and Surgery of Catania University. The literature documents only one homeopathic experiment, quoted by Clark and experimented by Burdick at the beginning of the XIX century on two varies (*Opuntia vulgaris* and *Opuntia spina alba*), using mother-tincture of flowers, only on two individuals.

MATERIAL AND METHODS

In the present research (June, 2001), with the help of Dr G. Parisi, agricultural specialist and expert in spontaneous plants, cladophills have been collected in more samples, all samples were taken from the Etna slopes, in the Belpasso, Nicolosi, and Ragalna (Catania). Hering company, specialized in homeopathic pharmacology, prepared the formulation: after the preparation of the mother-tincture, granules were prepared in 30 CH dilution, according to the rules of Good Homeopathic Factory.

The same company has been instructed to prepare granules used as placebo.

For the experimental study, 32 Caucasians volunteers were chosen of both sexes (n.17 males -n. 15 females) between 20 - 50 years old, weight not exceeding more or less 20% the ideal body weight (B.W.) reported in the "metropolitan height and weight" table. The study was

structured as follows: a screening visit, performed within two weeks before the start of the clinical phase, to evaluate healthy volunteers' eligibility.

Volunteers have been enrolled on the basis of the following inclusion criteria:

- Caucasian, male or female, healthy volunteers;
- age between 20 and 50 years;
- body weight within ± 20% of ideal B.W.;
- normal values of vital signs, ECG, physical findings and laboratory analysis;
- full comprehension and willingness to cooperate
- informed consent.

Volunteers have been excluded from the study according with the following criteria:

- allergy to drugs and chemicals

- previous or present renal, cardiovascular, gastro-enteric, hepatic, haematological, endocrine or CNS relevant diseases;

- use of drugs during the 4 weeks before the beginning of the experiment, because of possible interferences on the results of the homeopathic experiment.

- inclusion in another trials in the previous three months;
- blood donation during the 3 months prior to this study;
- history of drug or alcohol abuse

- unwillingness to cooperate or inability to comprehend the full nature and purpose of the study.

The study has been carried out according to the relevant principles of the Declaration of Helsinki and subsequent changes (Tokyo, 1975 - Venice, 1983 - Hong Kong, 1989) and general principles of Good Homeopathic Practice. After providing a detailed description of how the research would have been carried out, and adequate information about the dosage, the record of symptoms and purpose risks, individuals were asked to confirm their willing to participate.

EXPERIMENTAL TEAM

MONITOR:

Prof. Mario Matera (Department of Experimental and Clinical Pharmacology, Faculty

of Medicine and Surgery, Catania University.)

EXPERIMENTAL TRIAL MANAGER

Dr. Gaetano Arena (Homeopathic Doctor – Geriatrics – Ass." Tree Of The Life" - Ct)

LIABLE DOCTORS

Dr. M. Francesca Spada (Homeopathic Doctor - Nourishes - Ass."Tree Of The Life")

- Dr. Riccardo Nocifora (Homeopathic Doctor Cardiologist Pa)
- Dr. Gaetano Arena

PHARMACEUTICAL COMPANY AND SPONSOR:

Hering S.N.C. (Pozzallo- Rg)

EXPERIMENTAL PROTOCOL

The experiment was lead on 32 healthy volunteers, divided at random in two groups of 16 individuals each. Following the scheme, 16 individuals assumed the *verum* while the other 16 the *placebo*. Dosage: 3 granules morning and evening, distant from meals. Following the under mentioned protocol:

- 1. Screening visit for admission, following the above mentioned basis regarding admission and exclusion criteria.
- 2. The volunteers are treated randomly with the planning of Cochran and Cox, according to Schwartz and coll. method.
- 3. Registration of subjective symptoms for a week.
- 4. 1st day of study: subjects were administered prescribed medicine for 15 days, with daily registration of the symptoms relived.
- 5. Self-observation and record of symptoms for 15 days after the treatment.
- 6. Interview to the volunteers. Clinic test to point out the presence of any eventual side effects, farms controlled by the responsible doctors.

OVERALL STUDY DECRIPTION:

During a meeting that took place two weeks before the beginning of the experiment, participants were provided with a detailed description of the experiment. Each volunteer was then submitted to a medical visit at the harvest of the anamnesis in accordance with the homeopathic method, and some laboratory verifications were prescribed in order to accept instrumental examinations (haematology, clinical chemistry, urinalysis, and echografy).

During the week preceding the treatment, volunteers were asked to register symptoms, dividing them in three different levels: physical, emotional and mental.

4 volunteers belonging to the same group (bb2) abandoned the experiment for personal reasons.

The other individuals started the assumption of the remedy (*verum* or *placebo*) at the dose of 3 granules twice a day, for 15 days. They were asked to go on with their daily recording activity, so as to promptly underline the appearance of new important symptoms.

Volunteers were in daily contact with the investigator doctor and the director of the experimentation, treatments were immediately suspended at the appearance of new symptom.

Registers were taken and all the volunteers were called in a meeting to verify the data and the complete analysis of the symptoms of each one of them.

Final step consisted in the opening of each envelope with its attribution code, reuniting the obtained result with the *verum* and *placebo*. The 4 volunteers that abandoned the experiment were among those assuming the placebo.

OPUNTIA FICUS INDICA PATOGENESIS.

The subject that had take the placebo result, sporadically, diffused light symptom, of shot duration, yet had in the past linked to the all day living, at they own and medical judgment negligible under pathogenic aspect.

The characteristics of the experimentation through the voluntary that had taken *verum* were manifest in a relevant way only in 3 of them: C.N.S., apparatus gastrointestinal and urinary, the classification of symptom on 16 *verum* was fixed in one of the following group:

1 common symptom but short intensity

- 2 disappeared symptom
- 3 previous symptom reappearance
- 4 new symptom
- 5 exceptional symptom for intensity.

Was relief that 6 of the experimenters had some symptom provoke from the remedy that has go on till 5 days after the product suspension.

MIND

Was check in 7 provers a big mental tiredness ,and all had memory difficulty. the prover n 8 has report the between day 12 and 15 a big state of mental tiredness and confusion with anxiety and anguish instead the prover n 17 a great sense of mental tiredness confusion and irritability.

The number 20 mental tiredness, difficulty in remembering name of person and things read, in the studying; everything has appeared between day 2 and 13, so he suspended the treatment, the same symptom was annotated form the prover n 23 that has show a kind of covered with water head ,difficulty in remembering name of person everything was associate to a sense of dizziness, 3 prover has the same symptom but in a light way.

HEAD.

4 provers showed a diffused cephalalgia during the day 2 and in specially in the frontal part of the head. The prover n. 5 referred that he had a migraine with frontal heaviness.

STOMACH

6 provers had manifested a burning stomach symptom with feeling of vomit and lack of appetite especially during the late afternoon symptom expressed from the prover n 8 yet from day 3 till day 7 of proving and also from the prover number 17 further the symptom said before he said the he fell like a scare in his stomach, also the prover n. 27 further the burning felt lack of appetite and vomiting, the two provers said that the burning increased day by day with the experimentation till the point that the pain was so bad to discontinue the treatment.

ABDOMEN.

9 subjects felt diffused abdominal pain; in 4 at the intestinal level. 4 subjects has relief constipation and 2 diarrhoea two times a day, but without pain.

BLADDER AND URINARY APPARATE

6 subjects had manifest frequent urination .the experimenter n 10 refer that between day 2 till day 6 starts to fell a sense of urinary burning that increase hour by hour, with urinary urgency every 15-20 minutes and a presence of blood in urine, lumbar pain and a general sense of tiredness till to suspend the remedy.

Even the experimenter n 25 from day 3 till day 6 felt the need to urinate often. He said "during a trip in my car I had to stop many times to go to the toilette for small quantity of urine and after one day the burning and a great sense of vesical explosion occurred". She had a great pain in the back also, especially in the lumbar zone and also no sense of libido. the two experimenters felt symptom of cold during while urines and as they said a little bit of temperature.

The experimenter n 17, between day 4 and day 9 the continue sense of urine with a light burning during the urinating, no sense of libido and "watery sperm".

GENERAL SYMPTOMS

6 experimenters refer a sensation of general tiredness associate at urinary symptom, often with asthenia and mental confusion during the day.

PERSPIRATION

The experimenter n. 15 refer that from day 4 till day 8 further a sensation of tiredness and feeling empty, and a marked sense of perspiration at the extremity (feet and hands) the perspiration increase specially during physical and mental application with tiredness and general torpor.

The experimenter n. 17 from day 2 till day 5 referred perspiration at the extremity with a sense of coldness the symptom went back after 5 days from the break of the remedy.

SLEEP

2 provers showed insomnia in the first part of the night with tiredness during the day The experimenter n. 15 remembered very tidy dream for 3 nights.

CONCLUSIONS

The aforesaid 3 experimentation shows one more time with the study, carried out at 30 CH homeopathic dose using *verum versus placebo*, that further phytoterapic an clinical property said and well known the adding of new symptom, 103 in *verum* respect at 4 in placebo, and so the evolution of a substance sustain when is treated is homeopathically diluted and for this consequence the become of the therapeutic horizon.

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