INVESTIGATIVE STUDY OF BIOCHIMICAL EFFECTS OF LIFEWAVE PATCHES USING BIO-EXPLORER TECNOLOGY

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ABSTRACT

10 individuals suffering of chronic pain were followed over a period of twelve weeks. During the first eight weeks they have applied the LifeWave products, specifically IceWave Patches.
The study focused on subjective perception response, as measured by regular self-assessments with QUID, Italian Questionnaire of Pain, and focused on biochemical response, as measured by the BioExplorer method, an instrumental, non-invasive assessment of active biochemical processes occurring both in the cerebrospinal areas and in the inner organs of the human body.
The obtained results from this pilot study confirm the efficacy of LifeWave IceWave products as pain personal perception obtained in other previous studies and they underline specific modifications from the biochemical point of view: as concerns the molecules typically involved in the chronic inflammatory process, it was verified meaningful reduction of COX-2, PGE-2, PGF-2, IL-1 and lactic acid. It was highlighted also important reduction of neuropeptides Substance P and Vasoactive Intestinal Peptides (VIP). This pilot study suggests that the clinical effectiveness of IceWave Patches arises from real biohumoral changes induced by this products and it highlights a specific action of IceWave on the inflammation biochemical processes.

INTRODUCTION

Chronic pain is a complex clinical condition with no easy resolution, usually joined to chronic inflammatory processes.
Chronic inflammation is a long term biological process in which coexist the active inflammation, the tissue destruction and repair attempts.
Chronic inflammations could arise from a phlogogenic antigens persistence after an acute inflammation not completely resolved; it is possible that these agents can not be reached from the defense systems, or that the lytic substances are not able to digest them.
The inflammation chronic level is given from infiltration degree of mononuclear macrophages cells, lymphocytes and plasma cells and from the action induced from these inflammatory cells. The products released from these cells are many as: enzymes, plasma proteins, reactive oxygen species, arachidonic acid metabolites, cytokines, etc. Among these the arachidonic acid metabolites, leukotrienes and especially prostaglandins, seem to be the more responsible of the inflammatory clinic symptomatology [1, 2, 3, 4, 5, 6, 7].
The arachidonic acid is a precursor in the synthesis of eicosanoids. The production of these derivatives and their action in the body, are mainly known as the *cyclooxygenase pathway:* the chemical reactions and pathways by which prostaglandins are formed from arachidonic acid, and in which prostaglandin-

endoperoxide synthase (cyclooxygenase) catalyzes the committed step in the conversion of arachidonic acid to the prostaglandin-endoperoxides PGG2 and PGH2.

The prostaglandins are cyclopentane acids derivative of arachidonic acid, which play a biological primary role as mediators of the processes resulting from inflammations.
The prostaglandis formed quickly, exert their effects locally and are subsequently degraded enzymatically or by spontaneous decay, the mechanism of formation of prostaglandins is called via cyclooxygenase, of the main enzyme, the cyclooxygenase.
This last one acts on fat acids and converts arachidonic acid into prostaglandin endoperoxides (PGG2) which, in turn, is converted to PGH2.
During this step will form a free radical of the oxygen.
The PGH2 is converted enzymatically into three products:

- • *Thromboxane A2,* which is found mostly in platelets. This is a rather unstable compound that causes platelet aggregation and vasoconstriction;
- *Prostacyclin* or PGI2, which is located predominantly in vessels' wall, has opposite effects to those of Thromboxane A2, and inhibits platelet aggregation and acting as a vasodilator;
- prostaglandins PGD2, PGE2, PGF2, which are found in various parts of the body and represent the more stable metabolites, they exert different actions on the tone and permeability of blood vessels.

Inhibition of prostaglandin synthesis is the mechanism of action of a widespread class of anti-inflammatory drugs, analgesics and antipyretics: the FANS.
In addition to these mediators, the cytokines are of particular importance [8, 9, 10, 11, 12, 13, 14, 15, 16, 17], especially in relation to pain, such as neuropeptides are involved neuropeptides as Substance P [18, 19] and the Vasoactive Intestinal Peptide (VIP) [20, 21, 22, 23]

The aim of the present investigation is to contribute to the available scientific evidence regarding the clinical effectiveness of the IceWave products and the amount of biohumoral changes induced by the IceWave on mediators involved in the inflammation.

MATERIALS AND METHODS

The tools used for monitoring and verification are the following:

- LifeWave products: IceWave Patches.
- Bioexplorer methodology, for the biochemical structure analysis, used in every meeting during the treatment period and also in the follow-up meeting.
- Pain observation form (QUID, Italian Questionnaire of Pain), applied to individuals with chronic pain, used in every meeting during the treatment period with IceWave and during the follow-up, after four weeks from the end of LifeWave product use.
- SCL-90, Simptom Check List, general observation questionnaire on psychopathology elements, used in every meeting during the treatment period and during the follow-up.

The LifeWave products are "nontransdermal patches that are constructed from organic materials all GRAS listed (Generally Recognized as Safe by the FDA). LifeWave patches were specifically designed to passively reflect back into the body a portion of the electromagnetic frequencies that they are exposed to when placed on the body. A common analogy would be that of a mirror which reflects back visible light. It is the result of reflecting back into the body a specific portion of the energy being emitted by the body that the patches exhibit any effect.
Since none of the biological materials in the patches enter the body the mechanism of action of these medical devices is through thermal interaction between the patches and the body. Specific and different medical applications can be selected by changing

the composition of organic materials in the patches to reflect back into the body different portions of the infrared spectrum. The best analogy is to consider the patches to be like selective filtering mirrors. While the materials in the patches will absorb a wide band of infrared radiation, they will only reflect back a very small amount of specific frequency information, which is dependent upon the formulation of organic materials used in the patch product. The thermal mechanism of action makes LifeWave patches fall under the medical device classification of disposable hot and cold packs". [24]

The Bioexplorer method is a non-invasive detection technology developed by the Biophysics Research – Rome, which can detect the activity of the major cerebral areas as well as of the main organs and systems of the body by providing a detailed analysis aimed at the identification of circulating metabolites that serve as markers.
The Bioexplorer method has been devised to provide an instrumental, non-invasive assessment of active biochemical processes occurring both in the cerebrospinal areas and in the inner organs of the human body. The Bioexplorer has been specifically designed for the measurement of electrical currents spontaneously emitted by the body in specific points. These points are directly linked to the areas to the organs and systems to be examined. No external electrical stimulation or invasive procedures of any kind are employed. The device has been designed to provide the highest degree of reliability and repeatability of measurements**.**
The Bioexplorer employs an interferometry technique based on the principles of QED (Quantum Electro-Dynamics in Medicine), widely studied by quantum physics. To detect the presence of a specific molecule in an area of the body, the Bioexplorer records variations in the homeostasis regulation, as compared to baseline condition, in the body area to be examined. The detection process is carried out after stimulation of the external points with the electromagnetic field generated by a pure molecular standard placed in direct contact with the body.
The electromagnetic spectrum emitted by the pure molecular standard interacts with the electromagnetic spectrum of the identical molecule, when the same molecule is present in an unbound form (i.e. pathologic) in the area examined.
The device measures the variation in percentage of the amount of electrical current that is generated physiologically by the human body in specific points, which are directly linked to area of the body under investigation. The amount of current generated is directly proportional to the level of homeostatic regulation.
The level of variation occurred in the amount of electrical current generated as a reaction to the stimulation, indicates the relative quantity of the substance present in the area examined, in a range from 0 to 2000.
The information between the external measurement point and the corresponding cerebral or peripheral areas of the body is transferred along a continuum of liquid crystals lined up in the collagen fibers of the connective tissue. The transfer of information is made possible by coherence mechanisms of the portion of structured water present in the connective tissue. [25]

The QUID test (Italian Questionnaire of Pain) is an instrument used to measure quantity and quality of pain perception and to monitor therapy, prediction and evaluation of analgesic methods (pharmacotherapy, biofeedback, hypnosis, etc.).
It is composed of 42 indicators, grouped into 4 main classes (*S – sensory, A - affective, E - Evaluation, M - mixed*) and 16 subclasses, each consisting of a variable number of descriptors arranged in ascending order of intensity and to which corresponds a given score. [26]

The SCL-90 test (Symptom Check List) is a self-administered questionnaire which consists of 90 items. The test consists of 90 items eventually tested during the last week and was used to exclude psychopathology components on the study's participants.

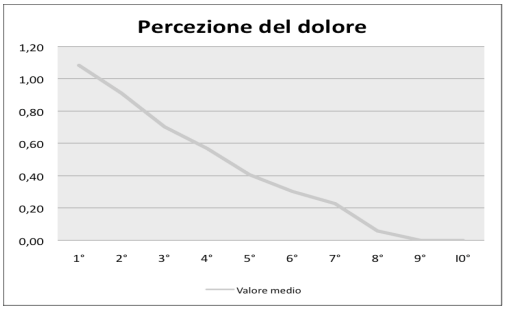
This pilot study was conducted in the following way:
Selected sample:
10 individuals suffering of chronic pain, total males, total female, aged between 33 and 70, with an average age of 47,4. In order to obtain a homogeneous sample were selected only subjects with chronic back pain, lasting at least 6 months. The subjects had not received drug therapy of any kind for at least 1 month and, for the duration of the study, did not take allopathic medicines or other, or have used other therapeutic practices, as osteopathic, chiropractic, acupuncture or other.
Those selected individuals were followed over a period of twelve weeks. During the first eight weeks we had applied the IceWave Patches. For each individual there was a total of twelve meetings:

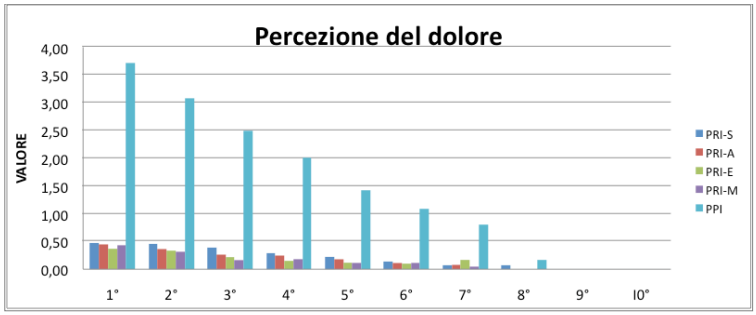
1) Starting selection. Initially we have given summary information on this study. Selection of the individual taking part to this study through evaluation of requirements by clinical interview.

2) A preliminary meeting, as explanatory and descriptive research moment, as well as valuation of the sample requirements. Phase of detailed explanation of research, goals, methodologies, different steps, operating characteristics of LifeWave products and their use. Training for the correct use of the products by the individual.
For this study the application of IceWave Patches was the following:
During the day the patches were placed in the area of pain, lumbar or cervical; during the night, the devices were applied at the point of "kidney 1" of the feet.
Overall, therefore, the devices were placed 24 hours a day.
3) Study central phase. For eight weeks the individual has used the IceWave Patches. In this period there was a weekly monitoring meeting during which was evaluated, through an interview and questionnaires, the clinical aspects and the subjective experience. During the same meeting was done analysis through Bioexplorer methodology, designed to evaluate the biochemical modifications of the subject.
View the location of the pain of selected subjects (cervical and low back), Bioexplorer measurements were performed on a total of 6 points, equivalent to the meridians of the bladder and kidney (right and left) and corresponding to the spinal cord (left and right sides).
At least 6 hours before measuring the patches were removed, in order not to interfere from the electromagnetic point of view with the measurement.
4) After one month from the end of the eight weeks, during which the individual has used the IceWave Patches, there was another follow-up meeting, during which there was a final clinical evaluation as well as with Bioexplorer methodology, in the same way as the previous monitoring meetings.

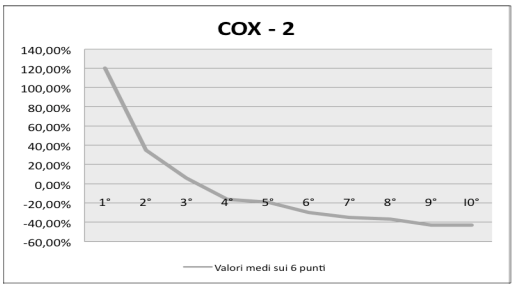
RESULTS

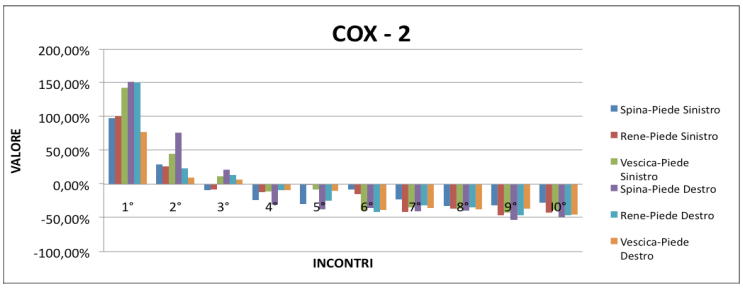
The data emerging from the subjective assessment of pain (QUID) showed a significant reduction of pain perception with a gradual trend during the 10 meetings.
The data obtained from measurements by Bioexplorer method showed significant reductions in all used points (spinal cord, bladder and kidney, left and right) of COX-2, PGF-2, PGE-2, Interleukin 1; lactide acid; Substance P and VIP.
This shows that IceWave Patches caused a specific reduction in the levels of inflammation's biochemical mediators.
From the data' analysis, through 10 meetings, the reductions have occurred within the first 3-4 weeks of IceWave Patches use, and remained stable in the following weeks of application.
Such reduction was maintained even after a month from the suspension of IceWave Patches, as shown by the follow-up meeting.
Herein under we can see the general graphs of changes obtained in 10 meetings.



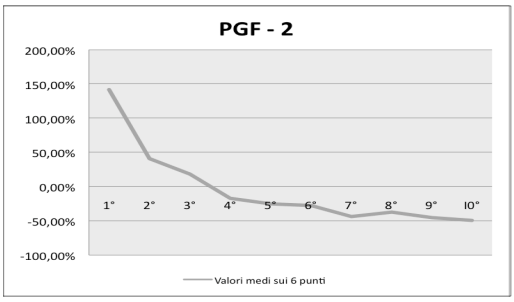


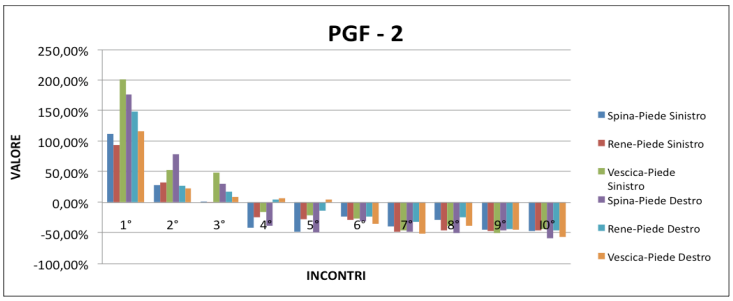
Perception of pain



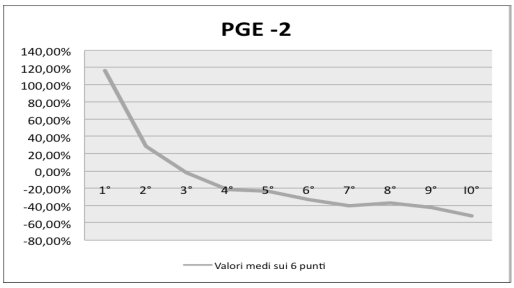


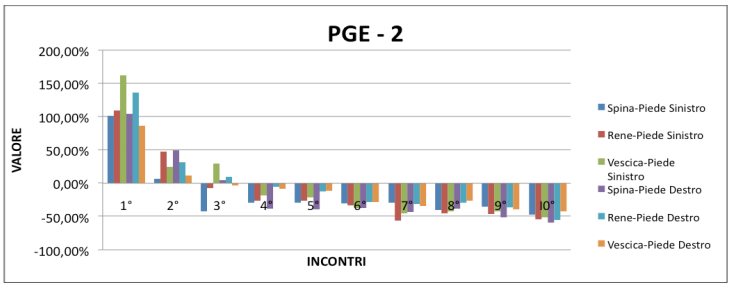
COX-2



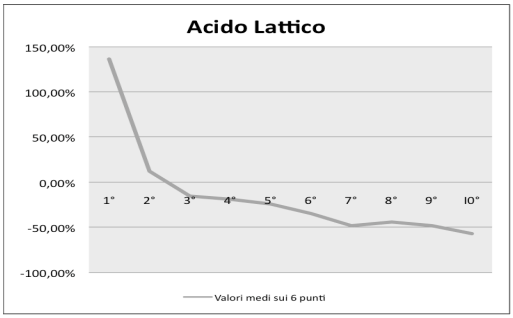


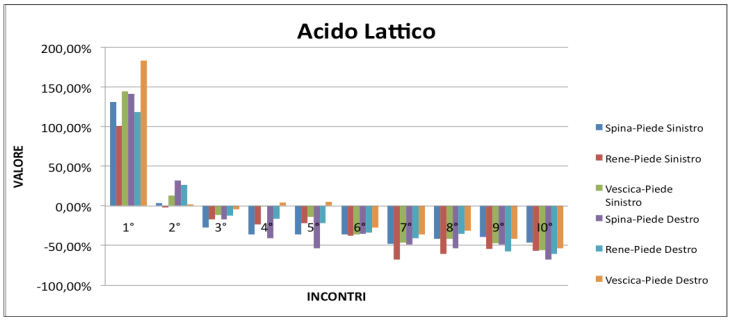
PGF-2



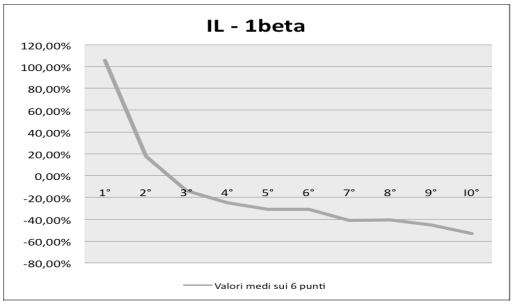


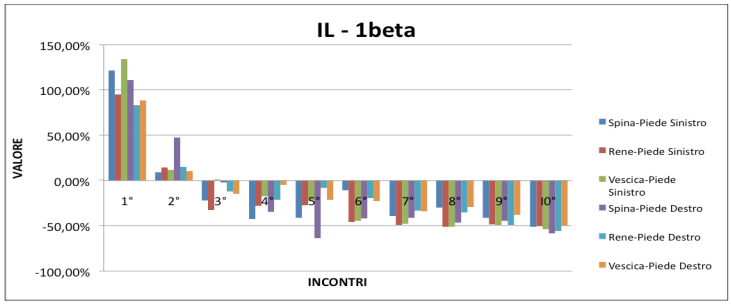
PGE-2



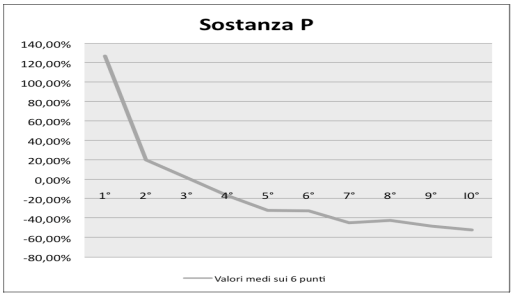


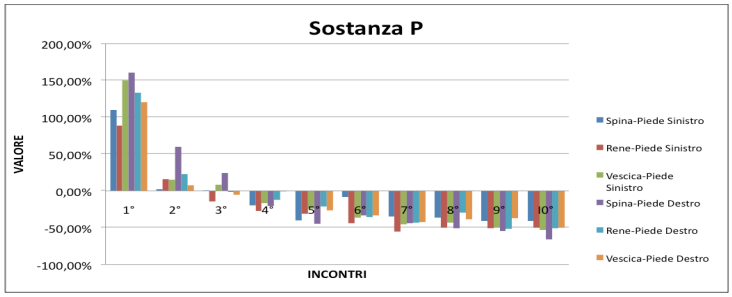
Lactic Acid



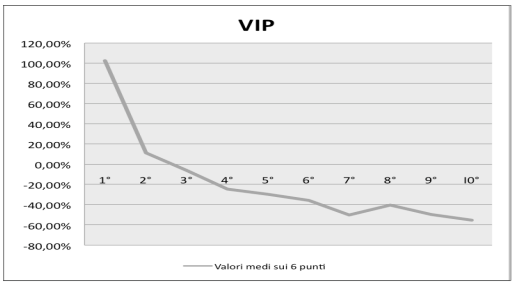


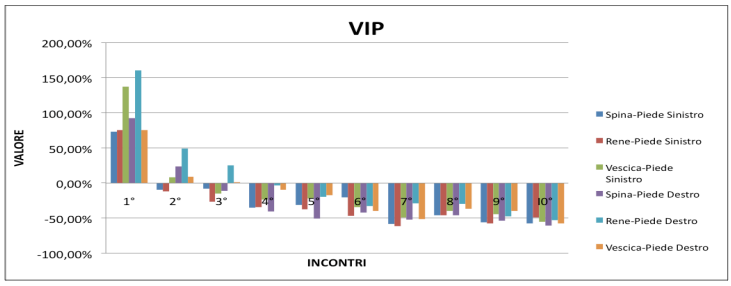
IL-1beta





Substance P





Vasoactive Intestinal Peptide (VIP)

DISCUSSION AND CONCLUSION

The obtained results from this pilot study confirm the efficacy of LifeWave IceWave products as pain personal perception obtained in other previous studies [27, 28, 29, 30, 31].

During the eight weeks of application of IceWave Patches there was a gradual decrease of pain, just begun, up to almost disappear by the end of all applications.

Such pain cessation was maintained even after discontinuation of applications of IceWave Patches.

The obtained results also underline specific modifications from the biochemical point of view: as concerns the molecules typically involved in the chronic inflammatory process, it was verified meaningful reduction of COX-2, PGE-2, PGF-2, IL-1 and lactic acid. It was highlighted also important reduction of neuropeptides Substance P and Vasoactive Intestinal Peptides (VIP).

It's interesting to see as the action of IceWave is particularly fast: the reduction of inflammation values markers occurred almost within 3 weeks, suggesting a specific effect of action.

This reduction was maintained throughout the time of application, but was maintained even after the suspension of IceWave Patches, suggesting, therefore, a stable effect over time and not just a temporary one.

This pilot study suggests that the clinical effectiveness of IceWave Patches arises from real biohumoral changes induced by this products and it highlights a specific action of

IceWave on the inflammation biochemical processes.
The sample was small and this study can be considered as a pilot study: the data suggest, however, a useful line of research to study the effects and mechanisms of the LifeWave Patches in bigger samples.

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