Prospective study of application of biological communication (cybernatics) in management of chronic low back pain – a preliminary report

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ABSTRACT

To observe the effects of application of cybernetics (theories of communication). This is an open level prospective study, involving patients with chronic low back pain of more than 3 months. Assessment were done before the start of therapy and after the completion of therapy every day for consecutive 6 days of treatment protocol. A total of 8 patients were enrolled (4 male, 4 female). The Visual Analogue Scale (VAS) was used to assess pain, Oswestry Disability Scale (ODI) was applied for scoring disability. ODI was scored at the start of treatment on 1st day and at the end of the treatment on 6th day. Mean VAS reduced from 8.12 to 6.93 after 1st day, which was also statistically significant (p<.01) .This trend continued and there was very significant reduction (p<.001) of VAS in the end when means were compared with pretreatment value. Mean Oswestry disability index reduced from 49.875 to 18.44 at the end of treatment which was statistically very significant (p <0.001). There were significant improvements in all the outcome measured after Scrambler therapy.

Keywords: Bio cybernatics, chronic low back pain VAS, ODI, Scrambler therapy.

INTRODUCTION

Pain is a protective phenomenon to avoid injury to the affected part of the body. Acute pain is relieved as soon as its purpose is served and the total system returns to the resting stage. In some cases medication like paracitamol and non steroidal anti inflammatory drugs (NSAIDS) are sufficient to relieve the pain. Some modality like transcuteneous electrical nerve stimulation (TENS) was also found to be effective.

But chronic pain is a problem to the attending physician to treat and also causes immense suffering to the patient. Chronic pain is itself a disease process and may be associated with continued pathology or may persist even after recovery from the primary disease or injury.[1]

The picture is same in case of low back pain (LBP). It is one of the important cause for seeking physicians consultation. It may be due to different causes like congenital deformity of vertebral column, trauma, and inflammation of other nearby skeleton and visceras. Majority of cases of LBP get relief from pain within few days with or without treatment.[2] But some LBP cases become chronic.[3] Initially the cases are treated symptomatically by NSAIDs, OPIODS and other different therapeutic modalities TENS. It was usual experience that all therapeutic modalities and medication gradually become ineffective so that patients seek alternate and complementary therapies.

The varieties of complimentary therapies included epidural anesthetic block, nucleolysis of the prolapsed intravertebral disc under fluoroscopic guidance etc. These intervention procedures require well equipped set up and expertise on the part of attending physician which is not always available. So there is a search for a modality which is simple, effective, non invasive and without side effects.

In bio-engineering, cybernetics deals with the theories of information (communication) and control. When these theories are applied to living system, it is called biocybernetics.[4] According to biocybernetics principles, pain is an information which is transmitted through transmission channel (nerve fibers) to central nervous system (CNS), which responds to it through a series of reactions. In acute pain, homeostatic equilibrium is rapidly restored as soon as pain information returns to silent state. But in chronic pain, either due to persistence of the cause of pain or for neuropathy, this homeostatic equilibrium is not restored. In that situation, complex reactions capable of modifying original information triggering the pain phenomenon (sensitization-autonomization) were seen. The result was gradual and complete ineffectiveness of all known therapeutic intervention.[5]

Scrambler therapy was based on the principles of biocybernetics. Here an artificial neuron is developed

Table-1: Showing vas score individual patient

Patient	Age/Sex	DAY 0	DAY 1	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6
I	36/M	9.0	7.5	7.1	6.1	4.8	4.2	3.8
II	43/F	7.4	6.3	5.8	4.9	4.2	3.7	3.5
III	67/F	8.0	6.7	6.3	5.0	4.5	4.0	3.4
IV	48/M	7.7	7.0	6.4	5.5	4.8	3.9	3.5
V	75/M	7.6	6.5	5.9	5.2	4.7	4.2	3.7
VI	50/M	8.3	7.1	6.1	5.3	4.9	4.1	3.7
VII	57/F	8.7	7.2	6.1	5.7	4.8	3.8	3.6
VIII	37/F	8.4	7.2	6.3	5.3	4.8	4.1	3.8
	MAX	9.0	7.5	7.1	6.1	4.9	4.2	3.8
	MIN	7.4	6.3	5.9	5.0	4.2	3.7	3.4
	MEAN	8.125	6.93	6.25	5.38	4.69	4.0	3.625

that produce a 'non pain' signal of such a characteristic that nervous system still recognizes the signal as 'self'. The result is masking of 'pain' signal with a dominant 'non pain' signal in the transmission channel (the nerve fibers). As a result CNS is able to modify the reflex adaptive response called Transcutaneous Electric Modulation Pain Reprocessore **(**TEMPR). Thus a homeostatic equilibrium is restored

Few available literatures showed remarkable improvement after scrambler therapy in visceral cancer pain, but no literature is so far available purely on chronic low back pain.

AIMS AND OBJECTIVE

To find out the efficacy of bio cybernatics in chronic low back pain. The assessment were done through VAS and ODI scale.

MATERIALS AND METHODS

The project had been cleared by the NRS Medical College's ethical committee where the study was conducted in the Department of Orthopaedics. The investigation was conducted in a week, where 8 patients fulfilled inclusion criteria out of 52 patients.

Inclusion criteria were

1. Chronic low back pain due to degenerative changes of spine with/without radiation to lower limb.
2. Very high baseline VAS (>7 in 10cm. VAS scale)

Exclusion criteria were

1. Psychosis
2. Low back pain of non-degenerative origin like spinal fracture, infection, inflammation or malignancy (primary or secondary)
3. Sensory deficiency on the skin areas where electrodes were placed
4. Pacemaker users

Informed consent was taken from each patient after explaining the treatment procedure in his or her vernacular language. Pain intensity was evaluated by a 10 cm. visual analogue scale (VAS). This linear scale is visual representation of pain as perceived by the patient. One end indicates absence of pain (marked '0') and other end represents worst imaginable pain (marked '10') and there was no other mark on the line (Fig. 4).

Each patient gave mark on the scale, depending on the intensity of pain, before and after each treatment session. Oswestry low back pain disability questionnaire was used to assess functional impairment. Oswestry disability index was used on a 0-5 point score to assess limitations of daily activities due to pain.[6]

The ODI index included:

1. Pain intensity, 2 .Personal care (washing, dressing),

3 .Lifting of weight, 4. Walking, 5. Sitting, 6. Standing,

7. Sleeping, 8. Sex life, 9. Social life, 10. Traveling

PROCEDURAL METHODOLOGY: Scrambler apparatus is a fully automatic multiprocessor apparatus able to stimulate five neurons artificially that allow five pain areas of the same patient to be treated at the same time. Application was done by single-use

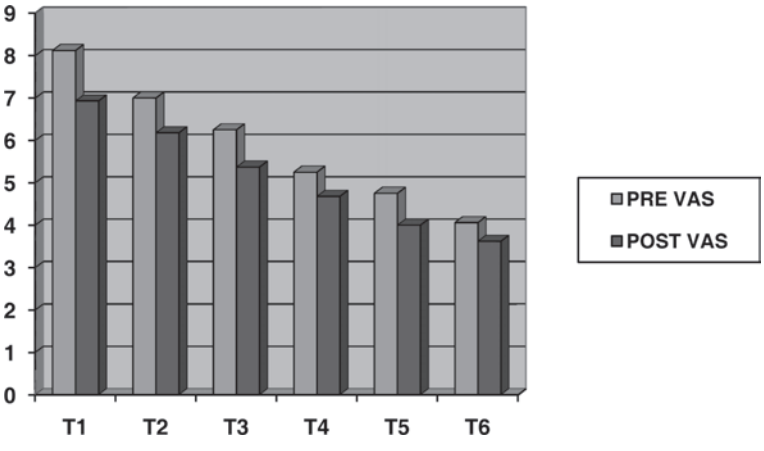

Fig. 1. Changes of VAS scores before and after each treatment session

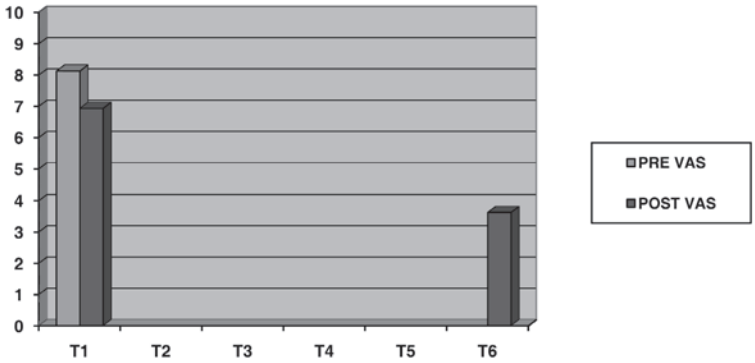

Fig. 2. VAS scores before and after completion of the study

Table-2: Showing odi score individual patient

Patient	Age/Sex	DAY 1	DAY 6
I	36/M	50	12
II	43/F	68	40
III	67/F	56	27
IV	48/M	35	17
V	75/M	62	15.5
VI	50/M	24	6
VII	57/F	54	17
VIII	37/F	50	13
	MAX	68	40
	MIN	24	6
	MEAN	49.875	18.44

surface electrodes which were applied to the areas of skin corresponding to pain. All parameters of stimulus were automatically regulated by the machine and only the intensity of the stimulus could be controlled manually. Single treatment session was given daily lasting for 45 minutes. For study purpose, a total of 6 treatment sessions were given to each patient. Pre treatment VAS and ODI score was recorded.

Subsequently post procedure VAS scoring was done every day and at the end of therapy. Second ODI score was taken on the last day.

Data thus accumulated were analyzed by SPSS 17.0 software. Statistical significance was analyzed by paired-t-test. Confidence interval was fixed at 95% and P value was compared with 0.05% probability.

RESULTS

A total of eight patients (male 4, female 4, mean age 51.62 yrs, range 36-75 yrs.) all suffering from chronic low back pain of degenerative origin and with radiation to lower limbs. Out of fifty-two (30 male and 22 female) patient with low back pain attended OPD on the previous week above 8 patients fulfilled the *inclusion / exclusion* criteria mentioned before. The mean duration of low back pain was 13 months with a maximum duration of 51 months to a min of 2 months.

VAS scores before and after each treatment session of each patient was shown in Table -1. Before starting the treatment mean VAS was 8.10 and after the 1st day treatment this value decreased to 6.95,at the end of 2nd day it was 6.25, at the end of 3rd day it was 5.38 which came down to 4.69 at 4th day and to 4.0 at the end 5th day. At the end of treatment on 6th day the mean VAS finally settled to 3.625 (Fig. 1).

Fig. 2 showed the cumulative effect of scrambler therapy which is depicted by a drop of pre treatment mean VAS from 8.125 to 6.93 on 1st day after therapy and finally to 3.63 at the end of treatment .The data were paired and analyzed by paired–t-test. The pretreatment mean when paired with post-treatment mean at 1st day it was found to be statistically significant ($p<.01$). But on pairing pretreatment mean at 1st day with mean at the 6th day difference was found to be very significant ($p<.001$).Which is an indicator of cumulative effect of scrambler therapy.

Oswestry low back pain disability score showed a significant improvement in functional status of the patients (Fig. 3). Reduction of Oswestry disability index from baseline value of 49.875 (24-68) to a value at the end of treatment was 18.44 (6-40) this when pared and compared was found to be statistically very significant ($p <0.000$) (Table -2). Fig. 4. showing the VAS score card from 0-10 index.

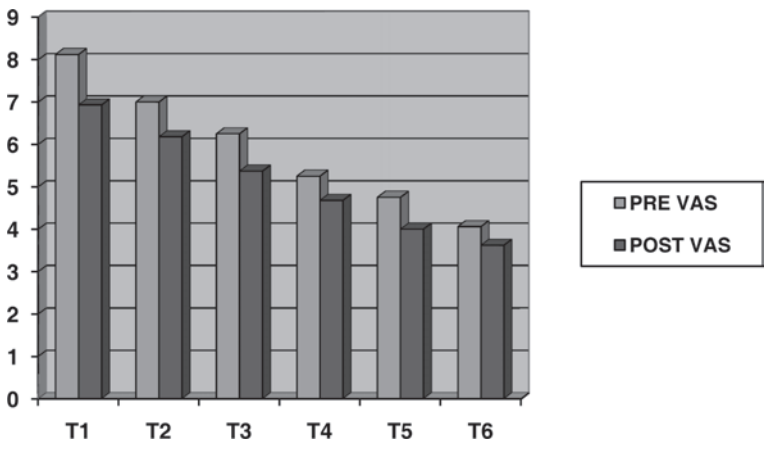

Fig. 3. Oswestry disability index scores before and after following treatment

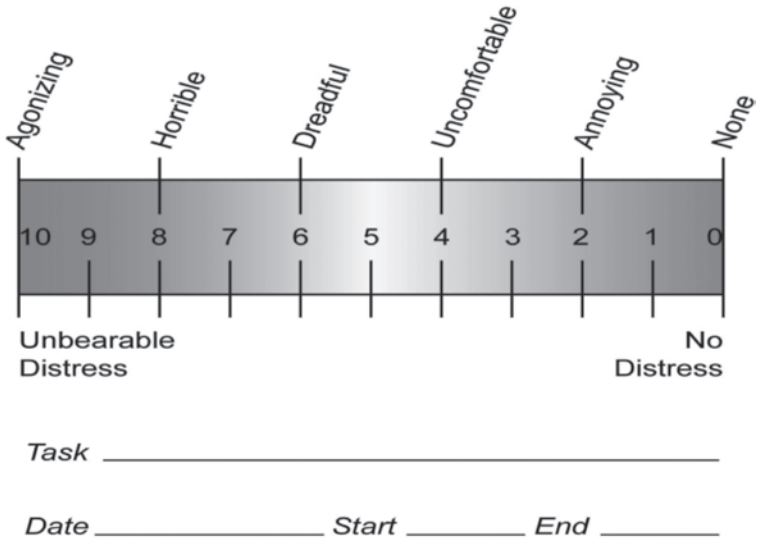

Fig 4. VAS score card

DISCUSSION

It is a noninvasive modality where non pain sensations are produced from artificial neuron and are transmitted through the transmission channel (peripheral nerves) by stimulating the body through surface electrodes.

The VAS scale used by us was simple, reproducible, not language dependent and easily understood by majority of the patients. Previous study indicated that scrambler therapy is helpful in visceral cancer patients[5] but no literature was available showing effectiveness of this therapy in chronic low back pain. An exponential dip in pain score on visual analogue scale for successive days was observed during the study which was an effect unlike other temporary electrotherapy modalities. If we observe the trend of change of VAS in subsequent treatment sessions, it was found that VAS scores gradually became lower and lower which indicated not only a gradual reduction of pain, but a re-adaptation of pain system, which is in agreement with the theoretical assumption. This might be explained by the fact that here perception of pain was not blocked in the transmission pathways as in TENS or other conventional treatment approached but by properties of pain information were controlled by manipulating a matavariable system [4] which was unique to this system.

During application of each treatment session of Scrambler therapy, all patients reported a rapid (within few minutes) disappearance of perception of pain, mean VAS came down from 8.10 to 3.625 in 6 days time. Compliance was excellent and no patient reported undesirable side effect.

Previous studies[4,5,7] showed remarkable improvements in visceral oncogenic pain. But there was no literature available regarding effectiveness of the scrambler therapy in pure musculoskeletal pain like low back pain done in our study.

Seven patients found such system of therapy much more acceptable then pills, needles or even long supervised exercise sessions, only one preferred pills to this modality. The main advantage is its non-invasive nature and feasibility of its application as a painless outpatient modality. The disadvantage is the high cost of installation and using of disposable electrodes which add to the cost. These were small but important aspects that came to our notice.

The present study showed that Scrambler therapy was also effective in chronic low back pain of degenerative origin both on the aspects of pain as well as on disability imparted by this condition. We could not find any data in the literature to compare with the present study. But it was evident that the sample size was too small and follow up data needs to be analyzed for its long term efficacy which this system of bio cybernatics may potentially achieve.

Our observation suggested that scrambler therapy is effective in controlling pain in chronic painful musculoskeletal condition like low back pain. It also reduced the disability resulted from pain. This was a preliminary study hence, before coming to any conclusion regarding the effectiveness of the scrambler therapy in musculoskeletal condition like chronic low back pain, extensive multi-centric controlled trail is needed.

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