

EVALUATION OF THE EFFICACY AND SAFETY OF A NEW HERBAL REVITALIZER REVIVIN

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ABSTRACT: *Clinical efficacy and safety of a herbomineral drug containing withania somnifera Asparagus racemosus glycyrrhiza glabra, mucuna pruriens, Myristica fragrans, Anauchus pyrethrum, Ipomoea digitata, sida cordifolia, zine ash complex and high energy carbohydrate molecules were evaluated in an open study. All patients treated with the drug reported good improvement in the various symptomatology of general weakness appetite, sleep mood, and concentration the overall improvement ranged between 69-77% The drug was well tolerated.*

INTRODUCTION

Traditional medicine uses herbal and mineral derivatives to normalize altered biochemical reactions and set the body systems working at tandem. Potent modern medicine has no particular cure for nonspecific ailments like tiredness, general weakness, lack of concentration, loss of appetite, fatigues insomnia and inability to perform under stress. Most commonly combination of vitamins nutrients and minerals are used to improve these symptoms combination of herbal drugs has been shown to improve these general non specific complaints in many patients.

Powder from the roots of Ashwagandha (*Withania somnifera*) was shown to have growth promoting properties in children and improve general debility and nervous exhaustion in adults (1) Powder of ashwagandha root mixed with ghee and honey in equal parts is also recommended for importance (2) Satvari or *Asparagus racemosus* has growth promoting properties (3). Roots of asparagus promote appetite (3) Extract from the roots of *Glycyrrhiza glabra*

is used as a tonic (4) *Mucuna prurines* (Kaunch beej) has been used to cure impotence (5) *Myristica fragrans* of jatiphal is an aphrodisiac and is used as a tonic for general debility (6) *Anacyclus pyrethrum* of Akarakara is regarded as a tonic to the nervous system (6) *Ipomoea digitata* (*Ksheera- kanda*) promotes growth and vigour in emaciated and debilitated children (4) *Sida cordifolia* (Balabeej) promotes health and general well being (1) Decoction of *S. cordifolia* root is used for increasing sexual power (6). In the present study, Revivin, a herbomineral capsule composed of *Withania sominfera*, *Asparagus racemosus*, *Glycrrhiza glabra*, *Mucuna pruriens*, *Myristica fragrans* *Anauchus pyrethrum*, *Ipomoea digitata*, *sida cordifolia*, zinc ash complex and High energy carbohydrate molecules was evaluated for its efficacy and safety as a revitalizer.

MATERIALS AND METHODS

In an open, uncontrolled study, total 251 patients (196 males & 55 females) mean age

44 years were enrolled to receive one capsule of reviving daily for 4 weeks. All patients requiring revitalizer for performance enhancement, concentration improvement, sexual dysfunction, fatigue and stress during convalescence from chronic illness were included in the study. Patients with severe illness and having evidence of any haematological biochemical and organic abnormalities were excluded from the study.

All patients received one capsule of reviving daily for 4 weeks. The effect of drug treatment was evaluated before and at the end of four weeks of therapy. Patients were asked to answer the detailed questionnaire for various symptomatology including malaise and weakness, appetite, sleep, sexual drive, mood, concentration. The various symptomatology including malaise and weakness, appetite, sleep sexual drive, mood concentration the various symptoms were evaluated using a four-point score where 0=none, 1=mild, 2=moderate and 3=severe degree. Occurrence of any side effects were recorded on the case record form.

RESULTS

In the present study, use of Revivin, one capsule daily for 4 weeks showed good improvement in various symptomatology of general weakness, appetite, mood and concentration. There was marked improvement in favour of various questions enquired about the subjective feeling in most of the patients, Revivin improved sense of well being, working capability and decreased lethargy in most of the patients. There was improvement in the capacity to work under stressful situations. Many patients reported feeling less tired at the end of the day's works after reviving. There was good improvement in appetite and sleep.

There was improvement in overall mental function and concentration.

Effect of reviving on various symptomatology evaluated with the help of questionnaire is shown in figure-1 before the therapy, large number of patients reported lethargy, large number of patients reported lethargy stressfulness and early fatigability. Many patients reported being unwell at the time of initiation of the therapy. As seen from the bar diagrams Revivin treatment significantly reduced these symptoms in many patients similarly more number of patients reported improvement in their appetite, sleep pattern reduction is sluggishness and improvement in their concentration after taking reviving for 4 weeks.

Most of the symptoms evaluated for mood like anxiety, restlessness irritability depression, nightmares improved in most of the patients (Table -1) As seen from the table, there was marked improvement in various symptomatology like weakness anxiety, restlessness, irritability and mood the overall improvement ranged from 96% - 77% (Figure-2). Irritability was reduced by 69% while weakness improved by 77%.

DISCUSSION

Drugs used in Ayurveda are derived from a wide range of materials like plants and minerals. In the present study, reviving, a combination of herbominerals, was indicated for performance enhancement, loss of concentration, appetite and weakness. Patients treated with this herbal revitalizer have recorded impressive improvement.

The goal of drug treatment was to improve the performance and overall well being of the patient. Treatment with Revivin significantly decreased symptoms of

weakness, restlessness, irritability etc by more than 70% from the baseline. *W. somnifera* and *A. racemosus* are known in Ayurveda to enhance immune functions and non-specific resistance to infections. Mortality due to gram positive gram negative and anaerobic infections were shown to be reduced significantly (7). Many plant preparations are described in Ayurveda to strengthen general host resistance.

Procedures of revitalization and rejuvenation were adopted in Ayurveda to increase the power of resistance to disease (increased immunity) and these procedures also retarded advancement of ageing(8).

In the present study, many patients reported improvement in sleep pattern and appetite, reduction of sluggishness, fatigability and increase in their concentration after four weeks treatment with reviving *S. cordifolia*, *W. somnifera*, and *A. racemosus* were some of the drugs described since charaka to keep off ageing and prevent diseases. Thus vitalizers, akin to antistress agents of plant origin are described in Ayurveda to act as inducers of enzyme systems like interferon (for fighting viral disease) and succinate dehydrogenase (SDH) enzyme responsible for the conservation and utilization of energy particularly during stress(9).

Immunomodulatory substances of varying chemical structures and molecular sizes exist in many of the plants, *W. Somnifera* is one such plant used in Ayurveda to prevent or treat disease through the restoration of healthy balance of life forces and an integrated relationship to the environment (10). This constituent of Revivin in earlier studies improved anxiety and mental function of patients (II). The drug reduces the level of acetylcholine and

catecholamines and increases the level of serotonin and histamine in brain tissue which may be a compensatory response to depletion of catecholamines (II).

M. fragrans was safely administered in insomnia where opium had failed and chloral contraindicated (6). It is prescribed as a tonic for general and sexual debility. A controlled trial with *M. fragrans* has shown improvement in 18 out of 30 patients complaining of premature ejaculation.

In the present study, reviving produced overall improvement in the various symptomatology like weakness, anxiety, depressed mood, insomnia between 69-77%. Only four out of 235 patients reported no improvement in well being after treatment with reviving. All patients tolerated Revivin well. None of patients complain of any adverse effects.

CONCLUSION

The present herbal revitalizer which is a composition of herbominerals improved appetite, weakness, concentration and enhanced performance. The initial trial proves that reviving keeps a person active and happy. None of the patients reported any side effect with Revivin and most of the patients have recorded impressive improvement. The limitation of the present study is its short duration and subjective evaluation. Further long duration, placebo controlled studies using objective parameters are required.

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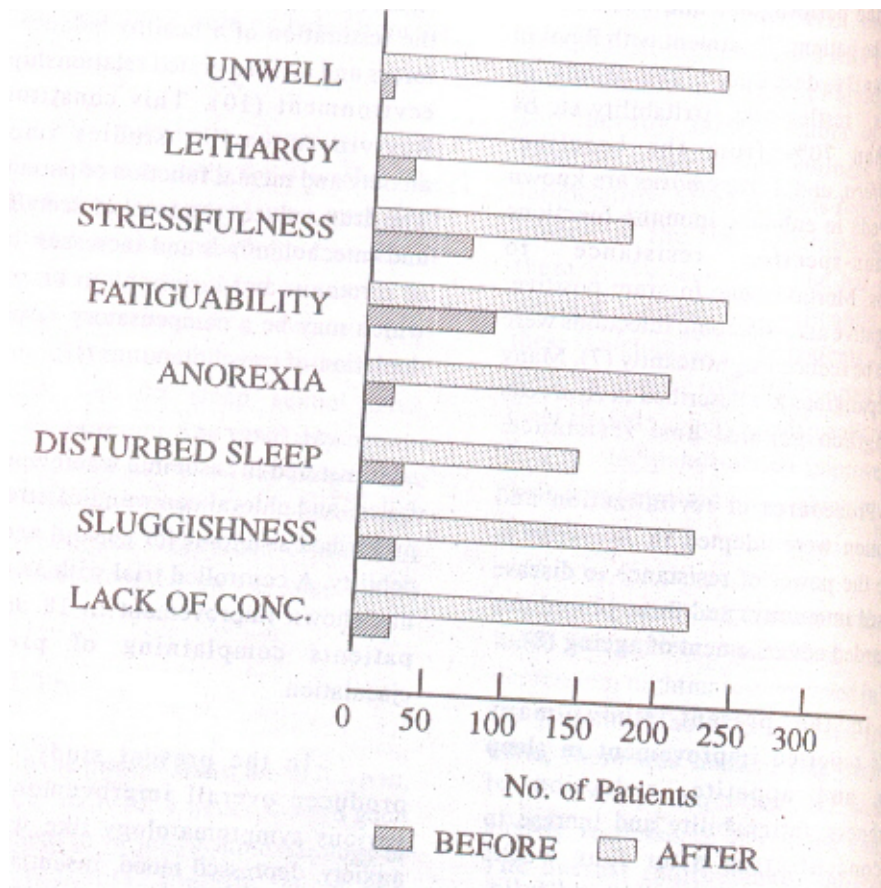


FIG 1: Effect of Revivin on the number of patients treated with various symptoms

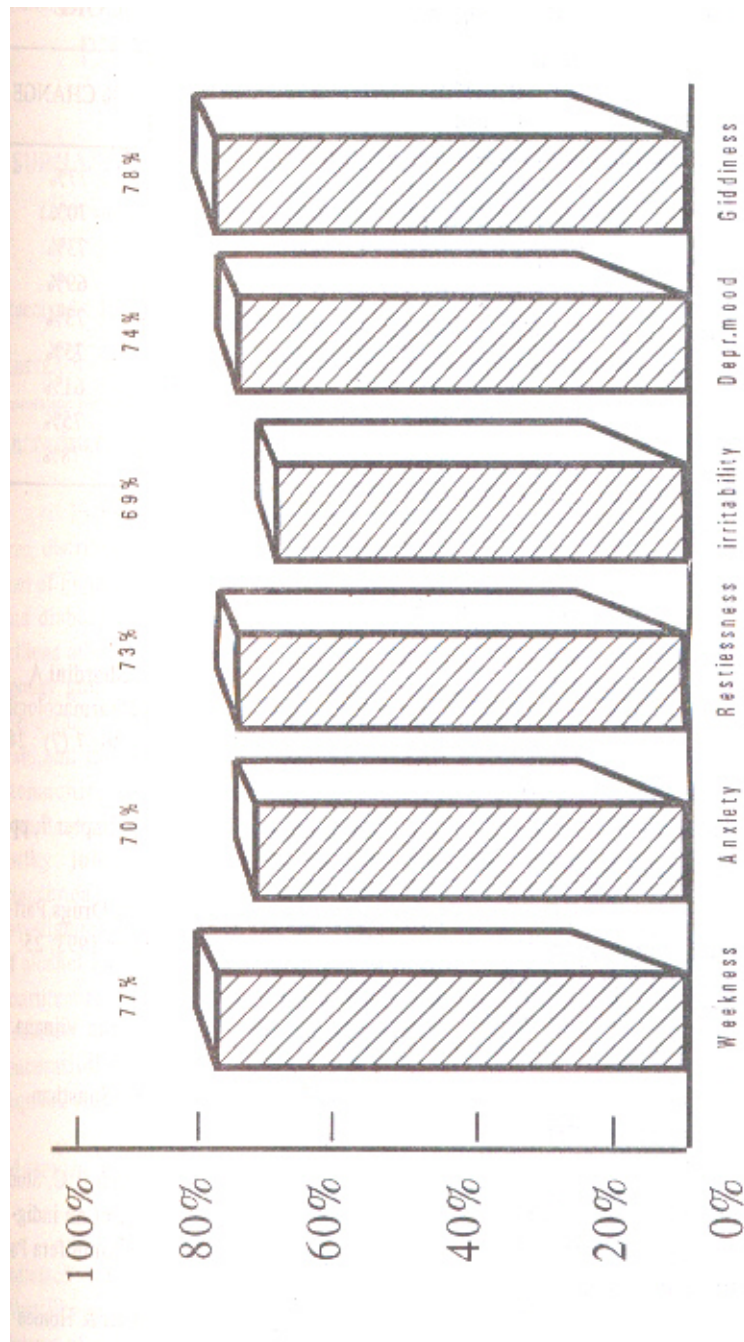


FIG 2 : Percentage change in the various symptom scores on treatment with Revivin

TABLE - 1
EFFECT OF REVIVING ON SYMPTOM EVALUATION SCORE

PARAMETERS	BEFORE M ±SD	AFTER M ±DS	% CHANGE
MALAISE / WEAKNESS	2.05 ± 0.82	0.47 ± 0.57	77%
ANXIETY	1.86 ± 0.88	0.55 ± 0.58	70%
RESTLESSNESS	1.52 ± 0.93	0.41 ± 0.57	73%
IRRITABILITY	1.57 ± 0.97	0.48 ± 0.61	69%

DEPRESSED MOOD	1.71 ± 0.94	0.45 ± 0.59	73%
NIGHTMRE	0.63± 0.85	0.16 ± 0.44	75%
SWEATING	0.88 ± 0.95	0.34 ± 0.61	61%
HEADACHE	1.21 ± 1.02	0.30 ± 0.55	75%
GIDDINESS	0.96 ± 0.89	0.21 ± 0.44	78%

Score: 0 = None 1= Mild 2 = Moderate 3= Severe

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