

EVOLUTION OF SUGGESTIVE RESPONSE OF PLACEBO TREATMENT ON GENERALIZED ANXIETY DISORDER

Nikunj D Patel¹, Sejal M Chaudhari²

¹MD Scholar, Department of Kayachikitsa, ²MD Scholar;
Department of Shalakytantra, Govt. Akhandanand Ayurveda College,
Ahmedabad, Gujarat, India

ABSTRACT

Introduction: A wide range of psychiatric conditions have been described in Ayurveda. Anxiety is a problem that ranges from mild uneasiness to distress in physical, mental & emotional setup. *Chittodvega* is applicable to illustrate whole anxious state and compared with Generalized Anxiety Disorder DSM-IV. *Chittodvega* patients given placebo to the therapeutically and healing effects of inert medicines and/or ritualistic or faith healing manipulations. **Aim:** To evaluate the efficacy of Placebo in management of Generalized Anxiety Disorders. **Material and Methods:** Total 15 patients were randomly selected for the study. Assessment was done based on Physical Symptoms, Positive and Negative *Manasabhava*, Hamilton Anxiety Rating Scale and Mini Mental State Examination. The data obtained in clinical study was analysed by using Wilcoxon Test. **Result:** Moderate improvement was 40%, while Mild improvement in 60% and none of the patients were remained unchanged. Effect of Therapy on Physical Symptoms of GAD *AtiChinta* relief 35.56%, *Arati* 45.00%, *Asahishunta* 37.18%, *Anavstichitam* 51.67%, *Snayu Dvestan* 30.95% and in *Klam* relief 69.70%. **Conclusion:** Placebo was effective on Generalized Anxiety Disorder and Placebo was improved disturbed *Manasabhava* of Patients of Generalized Anxiety Disorder.

Keywords: *Chittodvega*, Generalized Anxiety Disorders, *Mansabhava*, Placebo

INTRODUCTION

Ayurveda is one of the most ancient sciences of medicine in the world. This unique Ancient Indian Wisdom has survived vividly down the ages and is flourishing in the present times in newer dimensions attracting the attention; globally. It is pertinent to observe that psychiatry had roots in *Vedas* where *Bhootvidya* finds vivid mention. The contemporary *Ayurvedic* psychiatry consists of: (1) *Ayurvediya Manas Roga Vigyana* (2)

Bhootvidya. The mind or *Manas* is considered three dimensional: *Sattva*, *Rajas* and *Tama*.

According to *Ayurveda* mental health is a state of sensorial, mental and spiritual well-being. The mental ill health is brought about essentially as a result of unwholesome interaction between the individual and his environment.

A wide range of psychiatric condi-

tions have been described in Ayurveda like *Kama, Kodha, Lobha, Moha, Irsya, Mana, Mada, Soka, Chinta, Udvega, Bhaya, Harsha*. Moreover, other psychiatric conditions are also described in the classical literature caused by mixed *Samprapti* including both the *Sharirika* and *ManasDoshas*.

Anxiety is a problem that ranges from mild uneasiness to distress in physical, mental & emotional setup. The data suggest that in Anxiety Disorders Clinics approximately 12% of the individuals suffer with Generalized Anxiety Disorder¹. There are 4 million new case of Generalized Anxiety disorder per year². In India lifetime rates of anxiety disorders 17.6%³. According to *Ayurveda* Psychic factors are involved in almost all the disease processes along with physical trouble as both are interdependent. While describing psychosomatic disorders *Acharya Charaka* has quoted word *Chittodvega* along with *Kama, Krodha, Moha* etc.

Chittodvega is more applicable term to illustrate whole anxious state. Therefore in this study the term '*Chittodvega*' is compared with Generalized Anxiety Disorder DSM-IV, *Chittodvega* can exist as a separate disease or can be an etiological factor for other psychic and psychosomatic diseases.

Ayurveda has an age proved natural way for management of diseases. *Acharyas* have prescribed *Satvavajay* treatment (Mental health promoting) for the management of mental illnesses.

HYPOTHESIS:

H₀: There is no effect of Placebo the management of Generalized Anxiety Disorder.

H₁: There is effect of Placebo the management of Generalized Anxiety Disorder.

AIMS AND OBJECTS:

1. To evaluate the efficacy of Placebo management of Generalized Anxiety Disorders (GAD).

Materials and Methods:

- **Selection of the patients:** Patients were selected irrespective of caste, sex, profession etc. from O.P.D. and I.P.D. of Govt. Akhandanand Ayurveda College & Hospital, Ahmedabad and Govt. Maniben Ayurved Hospital, Ahmedabad.

- **Ethical clearance**

As this was a clinical research, Institutional Ethics Committee (IEC) approval was taken prior to initiation of research vide its letter No.21, DATED 07/04/2014. Adverse drug reaction (ADR) if any was duly noted and reported. Written consent of the present of each patient was taken before starting the treatment. Basic information of the disease and treatment was given to the patient. This trial is also registered in Clinical Trial Registry of India (CTRI), ref. No.CTRI/2016/04/006819 [Registered on: 19/08/2015]

- **Inclusion Criteria :**

- Diagnostic Criteria of Generalized Anxiety Disorder as per DSM-IV.
 - A. Excessive anxiety and worry (apprehensive expectation) occurring more days than not for at least 6 months about a number of events or activities.
 - B. The person finds it difficult to control worry.
 - C. The anxiety and worry are associated with three (or more) of following six symptoms.
 1. Restlessness
 2. Being easily fatigued
 3. Difficulty in concentration
 4. Irritability

5. Muscle tension
6. Sleep disturbance (difficulty in falling or staying sleep)

D. The anxiety, worry or physical symptoms resulting into significant distress or impairment in social, occupation or other important area of functioning.

➤ Patients >20 & <60 years of age.

Exclusion Criteria:

1. Social phobia
2. Obsessive compulsive disorder
3. Anorexia nervosa
4. Having major illness
5. Drug abuse
6. Hyperthyroidism.

PLAN OF STUDY:-

The research study was designed of Single blind study.

- Total 15 patients were randomly selected for the study and given placebo capsules (each of 500 mg) filled with maize starch powder in the dose of 2 gm /day in two equal divided doses at the same time and with the same *Anupan*.

CRITERIA FOR ASSESMENT:-

1. On the basis of relief in cardinal sign & symptom of disease.
2. Improvement on Hamilton's Anxiety Rating Scale and Mini Mental State Examination.
3. Relief in disturbed *Manasbhava* and *Manasa Vibrana Parikshya Bhava*.

STATISTICAL ANALYSIS:

The information gathered on the basis of above observations was subjected to statistical analysis. The Wilcoxon's signed-rank test was carried out for all non-parametric data to analyse the effect of individual therapy in the both groups.

The obtained results were interpreted as

1. Insignificant- $p > 0.05$
2. Significant- $p < 0.05$

3. Significant- $p < 0.01$
4. Highly significant- $p < 0.001$

Criteria for overall assessment:

The total effect of the therapy was assessed considering the following criteria.

- 1). Complete Remission: 81-100% relief in the signs & symptoms was considered as Complete Remission.
- 2). Markedly Improved: 61-80% relief in the signs & symptoms was considered as markedly improvement.
- 3). Moderate Improved: 41-60% relief was considered as moderate improvement in the signs & symptoms.
- 4). Mild Improvement: 21-40% relief in the signs & symptoms was considered as mild improvement.
- 5). Unchanged: 0-20% relief was considered as unchanged.

RESULT:

EFFECT OF THERAPIES

Placebo Group:

In this group of 15 patients were treated with placebo capsules (500 mg maize starch powder in the dose of 2 gm / day twice a day for 28 days).

Therapy provided significant results in Physical Symptoms 40.9% [Table-1]

Evaluating the therapeutic efficacy of placebo Negative *Manasabhava*, highly significant relief was observed in- *Vishada* (35.56%), *Shoka* (37.50%), *Hriya* (34.72). Significant improvement was observed in *Vashyata* (66.67%), *Rajah* (41.67%), *Moha* (56.06%), *Krodh* (42.86%), *Dweshha* (43.94%), *Bhaya* (39.29%), insignificant was *Upadhi* 83.33%, *Hriya* 34.72%. On Positive *Manasabhava*, it was revealed that, highly significant relief was observed in *Shraddha* (40.91%). Significant improvement was observed in *Avathana* (56.61%), *Medha* (30.30%), *Smriti* (55.56%), *Dhairya*

(57.58%), *Harsha* (56.67%), *Dhriti* (72.22%), *Vijnana* (75.00%), *Viryam* (71.43%) Insignificant *Shila* (38.89%), *Priti* (33.33%) [Table-2]

Evaluating the therapeutic efficacy of Placebo on *ManasVibharamParikshaBhav*, *ManaVibhrama* 35.90% relief, which was statistically significant ($p < 0.01$). *Bud-dhiVibhrama*: 25.64% relief, which was statistically insignificant ($p > 0.05$). *SandnyaVibhrama*: 36.90% relief, which was statistically insignificant ($p > 0.05$). *SmritiVibhrama*: 46.67 % relief was statistically significant ($p < 0.05$). *BhaktiVibhrama*: 36.67% relief was statistically significant ($p < 0.01$). *ShilaVibhrama*: 51.67% relief was statistically significant ($p < 0.01$). *ChestaVibhrama*: 33.33% relief was statistically insignificant ($p > 0.05$). *AacharaVibhrama* 85.71% relief was statistically significant ($p < 0.05$). [Table-3]

On MMSE, Orientation: Disturbance in orientation was not found. Registration: 26.67% relief, which was statistically significant ($p < 0.01$). Attention and calculation 22.33% relief, which was statistically highly significant ($p < 0.001$). Recall 26.67 % relief was statistically significant ($p < 0.01$). Language: Improper Language was not found. [Table-4]

On HARS, Anxious: 37.22% relief, which statistically significant ($p < 0.01$). Tension: 55.00% relief, which was statistically highly significant ($p < 0.001$). Fears: 41.11% relief, which was statistically significant ($p < 0.01$). Insomnia: 53.79% relief was statistically significant ($p < 0.01$). Intellectual (cognitive): 43.33% was statistically significant ($p < 0.01$). Depressed Mood: 53.33% relief was found which was statistically highly significant ($p < 0.001$). Somatic (Muscular):

70.56% relief but it was statistically highly significant ($p < 0.001$). Somatic (Sensory): Somatic sensory symptoms were not found. Cardiovascular Symptoms: Cardiovascular symptoms were not found. Respiratory Symptoms: 100% relief was found which statistically insignificant ($p > 0.05$). GI Symptoms: 93.75% relief, which was statistically significant ($p < 0.01$). Genito-Urinary Symptoms: Genito-urinary symptoms was not found. Autonomic Symptoms: Autonomic symptoms were not found. Behavior at Interview: 88.89% relief but it was statistically insignificant ($p > 0.05$). [Table-5]

OVERALL EFFECT OF THERAPIES:

In placebo group; 0% patients were markedly improved, 40% were moderately improved, 60% patients were Improved, 0% of patients remained. Unchanged and complete remission was found in none of the patient. [Table-6]

DISCUSSION

According to *Ayurveda*, the psychic factors are involved in almost all the disease processes along with physical disturbance as both of these are interdependent. While describing psychological disorders *Acharya Charaka* has quoted word *chittodvega* along with *Kama*, *Krodha*, *Moha* etc.

When *Alpa Sattva* (inadequate mental make-up or personality) person indulges in or is afflicted by *Manobhigata* and *Pragnaparadh*, it results in the imbalance of *ManasDosh* *Rajahand Tama* leading to the vitiation at bodily level by affecting *Prana*, *Udana*, *Vyana*, *Vayu*, *Sadhaka*, *Pitta* and *Tarpak*, *Kapha*, along with the vitiation of *Agni* & depletion of *Ojas* which present the psychosomatic presentation of disease.

Being alarming disease, it requires effective management. In recent years sev-

eral synthetic drugs have been introduced for the treatment of anxiety disorders. Although these drugs are having better results, one cannot avoid major side effects such as drug dependence, drug resistance, sedation etc.

CONCLUSION:

- Among various psychological disorders described in Ayurveda *Chittodvega* is nearest term for Generalized Anxiety Disorder DSM-IV.
- Placebo gives the results in sign and symptoms of GAD and on Hamilton Anxiety Rating Scale. It also provided improvement on the Mini Mental State Examinations along with clinical parameters of various *Manasbhavas* and *ManasVibharamaPariksha*.

➤ Thus it can be concluded that Placebo is effective in the management of Generalized Anxiety Disorder.

At the end of this study conclude that null hypothesis (H₀) is rejected and alternative hypothesis (H₁) is accepted.

There is effect of Placebo the management of Generalized Anxiety Disorder.

REFERENCES:

1. <http://www.ncbi.nlm.nih.gov/books/NBK83471/>
2. <http://www.nimh.nih.gov/health/statistics/prevalence/any-anxiety-disorder-among-adults.shtml>
3. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3146193/>

[Table-1] Effect of Therapy on Physical Symptoms

Sr. No.	Complaints	'n'	Mean score			%	W	P
			BT	AT	Diff.			
1	<i>AtiChinta</i>	15	2.93	1.93	1.00	35.56%	66	<0.001
2	<i>Arati</i>	10	1.80	1.10	0.70	45.00%	15	0.063
3	<i>Asahishunta</i>	13	2.23	1.38	0.85	37.18%	45	0.004
4	<i>Anidra</i>	8	2.13	0.88	1.25	56.25%	28	0.016
5	<i>Anavstichitam</i>	10	2.00	1.20	0.80	51.67%	28	0.016
6	<i>SnayuDvestan</i>	14	2.50	1.64	0.86	30.95%	36	0.008
7	<i>Klam</i>	11	1.64	0.64	1.00	69.70%	45	0.004

[Table-2] Effect of Therapy on Manasabhava

Sr. No.	Complaints	'n'	Mean score			%	W	P
			BT	AT	Diff.			
Negative Manasabhava								
1	<i>Vishada</i>	9	1.89	1.22	0.67	38.89%	15	0.063
2	<i>Vashyata</i>	4	1.50	0.50	1.00	66.67%	6	0.250
3	<i>Rajah</i>	14	1.71	1.07	0.64	41.67%	45	0.004
4	<i>Moha</i>	11	1.91	1.09	0.82	56.06%	36	0.008

5	<i>Krodha</i>	13	2.31	1.31	1.00	46.15%	45	0.004
6	<i>Shoka</i>	12	1.75	1.33	0.42	37.50%	15	0.063
7	<i>Dwesa</i>	11	1.73	1.00	0.73	43.94%	28	0.016
8	<i>Upadhi</i>	5	1.80	0.40	1.40	83.33%	15	0.063
9	<i>Bhaya</i>	14	1.86	1.14	0.71	39.29%	36	0.008
10	<i>Hriya</i>	12	1.67	1.17	0.50	34.72%	15	0.063
Positive Manasabhava								
11	<i>Avasthana</i>	13	1.38	0.77	0.62	56.41%	36	0.008
12	<i>Shraddha</i>	11	2.09	1.36	0.73	40.91%	21	0.031
13	<i>Medha</i>	11	2.45	1.73	0.73	30.30%	21	0.031
14	<i>Sangna</i>	-	-	-	-	-	-	-
15	<i>Smriti</i>	12	1.92	0.92	1.00	55.56%	55	0.002
16	<i>Dhairya</i>	11	1.45	0.73	0.73	57.58%	36	0.008
17	<i>Shila</i>	12	1.92	1.33	0.58	38.89%	15	0.063
18	<i>Harsha</i>	10	1.70	1.00	0.70	56.67%	21	0.031
19	<i>Priti</i>	10	1.90	1.40	0.50	33.33%	15	0.063
20	<i>Dhriti</i>	9	1.44	0.56	0.89	72.22%	28	0.016
21	<i>Vijnana</i>	6	1.50	0.50	1.00	75.00%	21	0.031
22	<i>Viryam</i>	7	1.71	0.71	1.00	71.43%	21	0.031

[Table-3] Effect of Therapy on MANAS VIBHARAMA PARIKSHA

Sr. No.	Complaints	'n'	Mean score			%	W	P
			BT	AT	Diff.			
1	<i>Mana Vibhrama</i>	13	2.69	1.85	0.85	35.90%	45	0.004
2	<i>BuddhiVibhrama</i>	13	2.08	1.62	0.46	25.64%	15	0.063
3	<i>SandhyaVibhrama</i>	14	2.21	1.50	0.71	36.90%	36	0.063
4	<i>SmritiVibhrama</i>	10	1.80	1.10	0.70	46.67%	21	0.031
5	<i>Bhakti Vibrama</i>	10	2.10	1.40	0.70	36.67%	15	0.063
6	<i>ShilaVibhrama</i>	10	1.90	1.00	0.90	51.67%	36	0.008
7	<i>ChestaVibrama</i>	12	1.83	1.33	0.50	33.33%	15	0.063

8	AacharaVibrama	7	1.43	0.29	1.14	85.71%	28	0.016
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[Table-4] Effect of Therapy on HDRS

Sr. No.	Complaints	'n'	Mean score			%	W	P
			BT	AT	Diff.			
1	Orientation	-	-	-	-	-	-	-
2	Registration	15	3.00	2.20	0.80	26.67%	55	0.002
3	Attention and calculation	15	4.53	3.47	1.07	22.33%	78	<0.001
4	Recall	15	3.00	2.20	0.80	26.67%	45	0.004
5	Language	-	-	-	-	-	-	-

[Table-5]Effect of Therapy on HDRS

Sr. No.	Complaints	'n'	Mean score			%	W	P
			BT	AT	Diff.			
1	Anxious	15	2.33	1.40	0.93	37.22%	55	0.002
2	Tension	15	2.07	1.13	0.93	55.00%	78	<0.001
3	Fears	15	2.13	1.33	0.80	41.11%	45	0.004
4	Insomnia	11	2.64	1.18	1.45	53.79%	45	0.004
5	Intellectual (cognitive)	15	2.13	1.27	0.87	43.33%	45	0.004
6	Depressed Mood	15	2.27	1.07	1.20	53.33%	66	<0.001
7	Somatic (Muscular)	15	1.80	0.73	1.07	70.56%	105	<0.001
8	Somatic (Sensory)	-	-	-	-	-	-	-
9	Cardiovascular Symptoms	-	-	-	-	-	-	-
10	Respiratory Symptoms	2	1.00	0.00	1.00	100.00%	3	0.5
11	Gastro-intestinal Symptoms	8	1.38	0.13	1.25	93.75%	36	0.008
12	Genito-Urinary Symptoms	-	-	-	-	-	-	-
13	Autonomic Symptoms	-	-	-	-	-	-	-

14	Behavior at Interview	3	2.33	0.33	2.00	88.89%	6	0.250
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[Table-6]Overall effect of therapy on 15 patients of Generalized Anxiety Disorder

Effects	Placebo Group	
	No. of Patients	%
Complete remission (81-100%)	-	-
Markedly improved (61-80%)	-	-
Moderate Improved (41-60%)	6	40%
Mild Improvement (21-40%)	9	60%
Unchanged (0-20%)	-	-

CORRESPONDING AUTHOR

Nikunj D Patel¹

MD Scholar, Department of Kayachikitsa,

Govt. Akhandanand Ayurveda College,

Ahmedabad, Gujarat, India

Email: n_patel@outlook.com

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