

A CONTROLLED CLINICAL STUDY TO EVALUATE THE COMBINED EFFECT OF TAGARADI TAILAM SHIRODHARA & BRAHMI ASHWAGANDHA CHURNA IN MANAGEMENT OF CHITTODVEGA VIZ -A VIZ ANXIETY

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Article Received on
14 August 2019,

Revised on 04 Sept. 2019,
Accepted on 24 Sept. 2019,

DOI: 10.20959/wjpr201911-15945

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ABSTRACT

In today's life everyone is trying to fulfill their physical desires, therefore today's metaphysical society is facing unsteady, weakened, hard and everyday changing lifestyle. The utmost gift of this is stressful life. Mental disorders are increasing day by day as a primary disorder or as a comorbid condition. Global burden of disease statistics indicate that 4 of the 10 most important causes of disease in psychiatric in origin. Anxiety is one of them which can be correlated to chittodvega. Although modern therapeutics has a spectrum of the drugs for the management of this disease, but they have serious side effects and habit forming nature. Ayurveda principle of treating Manas dosha is by improving satvaguna i.e., avoidance of Pradynaparadh, to control indriyas, to follow sadvrutta with the help of murdhini chikitsa &

medhya dravyas. In this study we have taken two groups each of 30 patients. Group A was given shirodhra with Tagaradi tailam (Tagar, Brahmi, Sankhpushpi, Jatamansi, Karpura) for 15 day followed by Brahmi & Ashwagandha churna orally for 15 days and Group B was given T. Alprazolam 0.5 mg HS for 30 days. Hamilton Anxiety Scale was used for assessment. Result were obtained using Unpaired T Test. Both Trial Group & Control Group showed Significant Result.

KEYWORDS: Anxiety, tagaradi tailam, Brahmi & Ashwagandha churna, Alprazolam.

INTRODUCTION

Ayurveda – an eternal science of healthy living treasures deals with Physical, Psychological and spiritual well being of the human being and covers all the aspect of human life. It is not a materialistic science but a philosophical and factual truth, which is enhanced by our great ancient sages, through their experience, logic and power of wisdom.

Human life is considered as the invaluable opportunity to achieve the prime goals of life viz., Dharma, Artha, Kama and Moksha. To achieve all four prime goals of life, so that they had smooth, sound, safe, assured, steady and healthy lifestyle. On the other hand today every one try to fulfil all the physical desires, therefore today's metaphysical society is facing unsteady, weakned, hard and everyday changing lifestyle. This gift of this life style, almost everyone appears to be stressed and confused, this reflection can lead to mental disability like anxiety disorder.

Anxiety is universal experience, which has important protective function in the face of danger. It becomes morbid when symptoms are out of proportion to external circumstances or if they persist long after a threatening situation has been averted. However, there is no clear distinction between the features of normal and pathological condition, the anxiety is the chief symptom and acting through the autonomic nervous system, produces all kinds of visceral symptoms.

In Ayurvedic literature anxiety disorder can be correlated with chittodvega. Acharya Charak mentioned Chittodvega (a psychiatric disorder due to vitiation of Raja and Tama dosha) in Vimansthan Roganikvimanam adhyaya. Chittodvega can be defined as a chitta (mind) + Udvega (anxiety) = chittodvega- 'Anxious status of mind' (Sanskrit – English Dictionary of Sir Monier Williams). In Ayurveda various psychological disorders are mentioned, which show some similarity with anxiety disorders. Chittodvega seems to be nearest term for anxiety disorders, which is one of the psychological disorders, which is one of the psychological disorder described by Charak (vi. 6/5).

Mental disorders are common in medical practice and may present either as a primary disorder or as a comorbid condition. Global burden of disease statistics indicate that 4 of the 10 most important causes of disease worldwide are psychiatric in origin. Psychological disorders affect normal body functioning and can produce somatic disorders which are known as psychomatic disorders, e.g., Peptic Ulcer, Irritable Bowel syndrome, ulcerative colitis,

cardiovascular symptoms (palpitations, chest pain). Now a days number of patients having psychosomatic disorders are increasing.

Although modern therapeutics has a spectrum of the drugs for management of this disease, they have serious side effects and habit forming nature. Therefore there is a wide scope of research to find out a safest remedy or non-pharmacological approach from ayurveda for the management of this disease.

Principle of treatment for manasdosha in ayurveda is to improve satvaguna by sattvavajaya chikitsa i.e., avoidance of pradnyaparadh, to control indriyas, to follow sadvrutta. Satva guna can be improved by decreasing vitiated raja and tama guna with help of Medhya dravya and murdhani chikitsa i.e., Shirodhara. It also help to decrease vitiated pran vayu and sadhak pitta, thus improves functioning of indriya and manasa. The drug under this trial i.e., tagaradi tailam contains tagar, brahmi, jatamansi, shankhapuspi and karpoor. Oral administration of Brahmi and ashwagandha churna is also Medhya in nature. Hence these drugs have all properties mentioned for manasadosha. They are helpful to break samprapti of chittodvega.

Keeping all these things in mind the study entitled “A controlled clinical study to evaluate the combined the effect of tagaradi tailam shirodhara & Brahmi, Ashwagandha churna in management of chittodveg viz-a- viz anxiety.” was undertaken. It was compared with a standard drug Alprazolam 0.25mg given at night for 1 month.

SAMPRAPTI - Pathogenesis of Chittodvega

Chittodvega is a mental disorder which originates by involving different factors like dosha, dushya, Agni, Srotas etc., which are being explained here in detail. Due to Nidana sevana i.e., Asatmendriyarthasamyog, Prajanaparadh and Parinama, Manasa Dosha i.e., Raja and Tama and Sharira Dosha Vata, Pitta and Kapha are vitiated. Prana, Udana and Vyan vayu, Sadhak Pitta and Tarpak Kapha are comparatively more vitiated among subtypes of sharira dosha. Vitiated Raja and Tama go to Hridaya and Vitiates it. Due to Ashraya Ashrayibhava mana is also vitiated, because its seat is in Hrudaya. Vitiated mana by involving manovaha srotas produces Mansika Lakshana of chittodvega.

Vitiation of Prana, Udana and Vyan vayu, Sadhaka Pitta and Tarpak kapha lead to mano dusti and produce conditions like Indriyopaghata, Utsahabhramsha, Chittoplava etc. (A.H. Ni-16). Vatadi Doshas vitiate jathargni and after Rasadi Dhatu vitiation their respective srotas are

also vitiated leads to the various somatic symptoms found in chittodvega. Hence, Chittodvega have both psychic and somatic manifestation.

SAMPRAPTI GHATAKA

1. Dosha - Manas – Raja, Tama.
2. Sharir - Vata - Prana, Udana & Vyana.
3. Pitaa – Sadhaka.
4. Kapha – Tarpak.
5. Dushya – Mana.
6. Agni – Jatharagni – Manda, Vishama.
7. Srotas – Manovaha strotodusti.
8. Udbhava Sthana – Hridaya and Mastishka.
9. Vyakti Sthana – Mana and Sharir.
10. Sadhya Sadhyata – Krucchra Sadhya.
11. Updrava – Unmadadi Monovikara.
12. Sarva Shariravikara.

AIM AND OBJECTIVES

AIM

To study the possible mechanism of action of TAGARADI TAILAM & brahmi, ashwagandha churna in chittodvega.

OBJECTIVES

1. To study the clinical picture of anxiety.
2. To evaluate efficacy of Tagaradi Tailam shirodhara and bramhi, ashwagandha churna in chittodvega i.e., mild to moderate anxiety.
3. To compare the efficacy of tagaradi tailam shirodhara & bhramhi, ashwagandha churna in mild to moderate anxiety with established drug Alprazolam.

MATERIALS AND METHODS

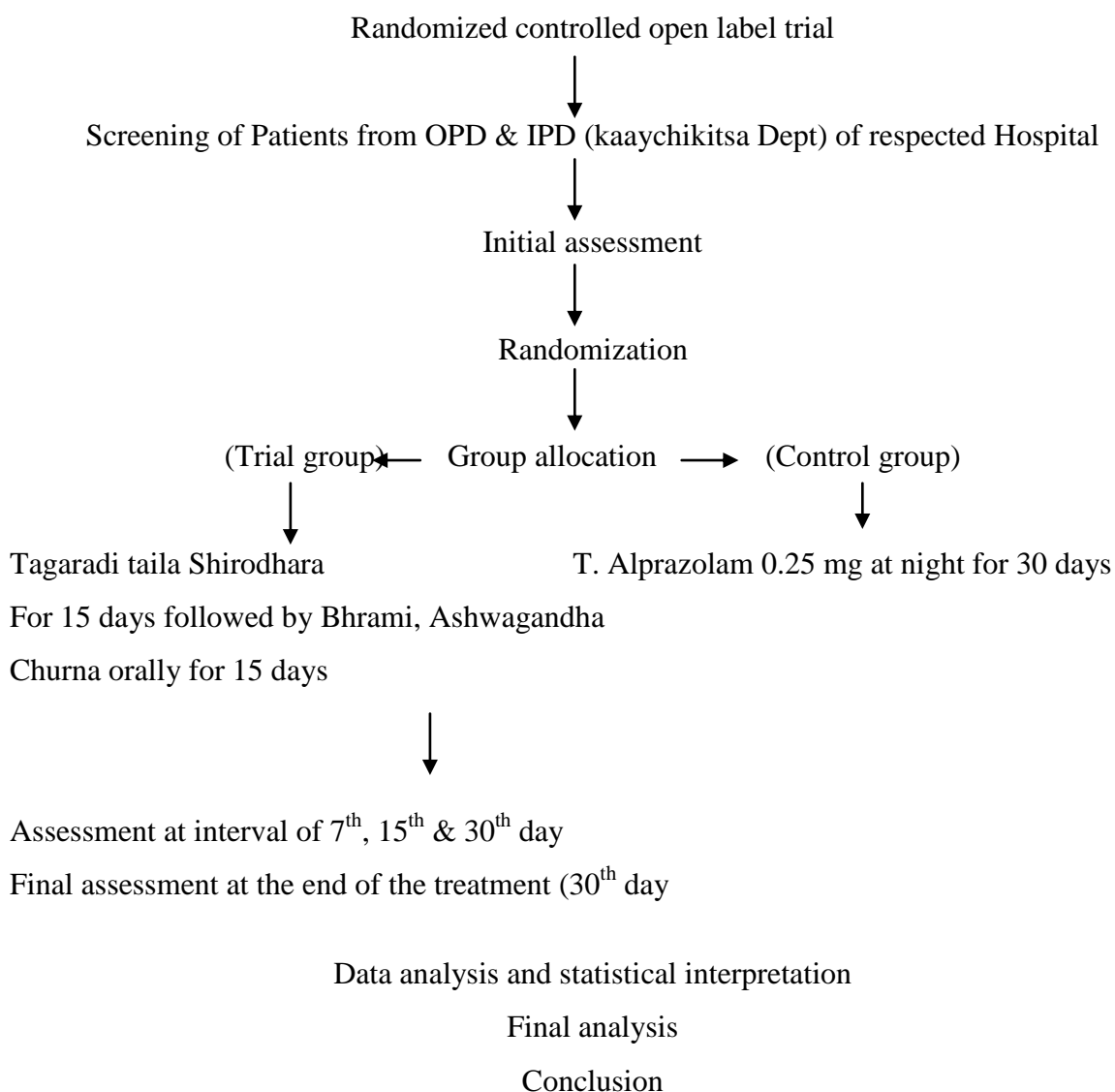
Study type - Prospective, Open Randomized, Controlled.

Medium of Dissertation - English supplemented by ayurvedic terminologies whenever necessary in Sanskrit.

CLINICAL STUDY

60 patients having chittodvega (mild to moderate anxiety) were selected for the research workout of which 30 patients were randomly included in trial group and 30 patients were randomly included in control group. Clinical trials were conducted on them. The data obtained from the trial was analyzed with proper statistical method and the results are presented.

TRIAL DESIGN



SELECTION OF PATIENTS

INCLUSION CRITERIA

1. Age - 17 to 65 years.
2. Sex – Male and Female.

3. Patient suffering from mild to moderate anxiety and stress (who achieve score between 18 – 24 points on the Hamilton scale for anxiety).

EXCLUSION CRITERIA

1. Subjects suffering from depression, schizophrenia.
2. Uncontrolled Diabetes Mellitus, Cardiac disease, Renal, Hepatic disorders.
3. Cases of HIV Positive.
4. Subjects addicted to alcohol and drugs.
5. Subjects who are using any any medications that could interfere with the effect of drug i.e., sedatives, antipsychotics etc.
6. Subjects whose ECG demonstrate any sign of uncontrolled arrhythmia/acute ischemia.
7. Subjects suffering from chronic contagious disease e.g., Hep C or Tuberculosis.
8. Pregnant or lactating mother.

INVESTIGATION

1. CBC Test.
2. BSL fasting and Postprandial.
3. HIV, VDRL.
4. ECG.

GROUPS

The selected 60 patients were randomly allotted to two groups:

1. Trial Group (Group A).

30 patients were treated with

- a) Tagaradi Tail shirodhara for 15 days followed by
- b) Bramhi, ashwagandha churna (1.5gms twice daily) orally for 15 days.

Method of Tagaradi tail preparation.

Swaras of Bramhi – 4 parts

Kwath of tagar, Jatamansi, Shankhapispi – 4 parts

Teel tailam- 1 parts

The mixture is heated till samyak taila siddhi lakshanas are achieved.

Karpoor is added as Prakshep dravya.

- 1) Control Group (Group B)

30 patients were treated with T.Alprazolam 0.25mg for 30 days.

CRITERIA FOR ASSESMENT

Assesment of patients have been done subjectively by Hamilton's Anxiety Scale.

1. Anxious Mood	Worries, anticipation of the worst, fearful anticipation, irritability
2. Tension	Feeling of tension, fatigability, startle response, moved to tears easily, trembling, feeling of Restlessness, inability to relax
3.Fears	Of dark, of strangers, of being left alone, of animals, of traffic, of crowds
4.Insomnia	Difficulty in falling asleep, broken sleep, unsatisfying sleep, fatigue on waking, dreams Nightmares, night terrors
5.Intellectual	Difficulty in concentration, Poor Memory
6.Depressed mood	Loss of interest, Lack of pleasure in hobbies, Depression, early waking, diurnal swing
7.Somatic(muscular)	Pains and aches, twitching, stiffness, myoclonic jerks, grinding of teeth, unsteady voice, increased muscular tone
8.Somatic (sensory)	Tinnitus, blurring of vision, hot and cold flushes, feeling of weakness, pricking sensation
9.Cardiovascular Symptoms	Tachycardia, Palpitations, pain in chest, throbbing of vessels, fainting feeling, missing beats.
10. Respiratory Symptoms	Pressure or constriction in chest, choking feeling, sighing and dyspnea
11.Gastrointestinal Symptoms	Difficulty in swallowing, mild abdominal pain, burning sensations, abdominal fullness, nausea, vomiting, borborygmi, looseness of bowels, loss of weight, constipation
12.Genitourinary Symptoms	Frequency of micturition, urgency of micturition, amenorrhea, menorrhagia, development of frigidity, premature ejaculation, loss of libido, impotence
13. Autonomic Symptoms	Dry mouth, flushing, Pallor, tendency to sweat, giddiness, tension headache, raising of hair
14.Behaviour at Interview	Fidgeting, restlessness and pacing, tremor of hands, furrowed brow, strained face, sighing or rapid respiration, facial pallor, swallowing etc.,

SCORING OF SYMPTOMS

Absent- 0

Mild- 1

Moderate- 2

Severe- 3

Very Severe- 4

Total Scoring

Mild Anxiety – 18

Mild to Moderate- 18- 24

The score was obtained on 0th, 7th, 15th, and 30th day.

OBSERVATIONS AND RESULT

GROUP	A	B	TOTAL
No. of total patients	32	33	65
Patients dropped out	2	3	5
Patients remained till end	30	30	60

Effect of therapy on symptoms score in patients of trial group

Sr No.	Symptoms	BT	AT	Diff	% Relief
1.	Anxious Mood	59	30	29	49.15
2.	Tension	57	27	30	52.63
3.	Fears	50	15	35	70
4.	Insomnia	60	26	34	56.67
5.	Intellectual	51	25	26	50.98
6.	Depressed Mood	51	26	25	49.01
7.	Somatic (Muscular)	38	14	28	73.68
8.	Somatic (Sensory)	46	16	30	65.21
9.	Cardiovascular symptoms	33	15	18	54.54
10.	Respiratory symptoms	39	13	26	66.67
11.	Gastrointestinal symptoms	35	15	20	57.14
12.	Genitourinary symptoms	33	10	23	69.69
13.	Autonomic symptoms	41	13	28	68.29
14.	Behaviour at interview	45	16	29	64.44
	Average score	45.78	18.64	27.14	59.28

Effect of therapy on symptoms score in patients of control group

Sr No.	Symptoms	BT	AT	Diff	% Relief
1.	Anxious Mood	62	38	24	38.70
2.	Tension	61	33	28	45.90
3.	Fears	59	26	33	55.93
4.	Insomnia	60	27	33	55
5.	Intellectual	35	12	23	65.71
6.	Depressed Mood	45	15	30	66.67
7.	Somatic (Muscular)	28	9	19	67.85
8.	Somatic (Sensory)	47	13	34	72.34
9.	Cardiovascular symptoms	17	7	10	58.82
10.	Respiratory symptoms	47	15	32	68.08
11.	Gastrointestinal symptoms	43	14	29	67.44
12.	Genitourinary symptoms	30	13	17	56.67
13.	Autonomic symptoms	50	19	31	62
14.	Behaviour at interview	55	19	36	65.45
	Average score	45.64	18.64	27	59.15

Effect of therapy on symptoms score

It was observed that overall % relief was slightly more in trial group (59.28%) than in control group (59.15%).

The total effect of therapy in Group A was statistically significant $P < 0.0001$ by using wilcoxon signed rank test.

The total effect therapy in Group B was statistically significant $P < 0.0001$ by using wilcoxon signed rank test.

Comparison between two groups with respect to symptoms score recorded before treatment by Mann-Whitney's Test:

This is performed to show homogeneity of the data between two groups. The test is applied to major symptoms in Hamilton's anxiety rating scale. The value of P in all symptoms is >0.05 which is statistically insignificant. It shows that gradation of symptoms in both groups are at same level. It means the data is homogenous in nature.

DISCUSSION

Chittodvega is a Manasavikara described by Charak (Cha. Vi. 6/5) has been considered as a perfect word for highlighting the status of anxiety. Various texts have also been described many terms related to mental status viz. Chittavibhramsa, chittanasa, chittavibhrama, Chittaviparyaya, Anvashita chitta etc. But, chittodvega seems to be more appropriate for the anxiety disorder.

Raja and Tama are the main Doshas of chittodvega. Prana, Udana and Vyan Vayu. Sadhaka Pitta and Tarpaka Kapha also play major role in the pathogenesis of chittodvega, due to their functions pertaining to Manas. Hrudya is also vitiated due to Ashraya- Ashrayi Bhava of Manasa. Manovaha Srotas is also vitiated due to transportation channel of Manasa. Rasadidhatu Dusti, Agni Dusti and Srotas Dusti have been also considered in its pathogenesis. Psychosomatic symptoms e.g. CVS, Respiratory, GIT, genitourinary symptoms are observed in chittodvega. Samhitakar Acharyas have mentioned various Medhya dravyas. Vagbhata has mentioned Murdhni Tailam (Va. Su. - 22/23). Keeping all this in mind an attempt has been made to evaluate the role of Tagaradi Tailam Shirodhara and Brahmi, Ashwagandha Churna in the management of Chittodvega.

Shirodhara of Tagaradi tailam helps in soothing vitiated doshas. Prana vayu gets vitiated (Kshobha) by its chala, Laghu and ruksha guna . Hence guru and snigdha gunatmaka tagaradi tailam helps in pacification of vrudha Prana Vayu. Shirodhara of sheeta viryatmaka tagaradi tailam helps in decreasing ushna and tikshana guna of sadhaka pitta. Tagaradi tailam hence nourishes tarpak kapha. Being snigdha gunatmaka and madhura vipaki combination of brahmi and ashwagandha Churna decrease vitiated Chala, laghu and ruksha guna of prana vayu. It also decrease ushna and tikshana guna of Sadhaka pitta by Madhura vipaka and tikta, Madhura rasa.

Thus Shirodhara of tagaradi tailam and brahmi, ashwagandha churna help to decrease symptoms of chittodvega.

CONCLUSION

Based upon the results of the clinical study following conclusions are drawn:

1. Majority of the patients were from age group 41-50 yrs.
2. Most of the patients included in this study were of vata- kapha and pitta Kapha Prakriti.
3. Majority of patients (66.67%) were of Rajasa Prakriti.
4. Maximum number of Patients (46.67%) were doing service.
5. Most of the patients were educated and 86.67% were married.
6. 58.33% patients were free from any kind of addiction, other had some sort such as taking Tea/coffee, Smoking, Tobacco etc.,
7. 81.67% patients were taking mixed diet i.e., non vegetarian as well as vegetarian diet.
8. Most of the patients i.e., (46.67%) have mandagni.
9. Most of the patients (53.34%) were having Krura Kostha.
10. Majority of patients (65%) were having Avara satva.

A significant improvement was observed in symptoms of patients from trial and control group. Hence it is concluded that both Trial & Control are equally effective in treating these symptomatic conditions.

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