World Journal of Pharmaceutical and Life Sciences
WJPLS
www.wjpls.org
SJIF Impact Factor: 6.129

EFFECTS OF *SHIRODHARA* IN GENERALIZED ANXIETY DISORDER

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Article Received on 30/09/2020 **Article Revised on 20/10/2020** **Article Accepted on 10/11/2020**

ABSTRACT
Anxiety is a common clinical presentation. Primary anxiety poses a significant problem in its management. Many among the current treatment options of anxiety are habit forming causing significant withdrawal symptoms. There are dose dependent responses often associated with drug adversities. Day time sedation is an undesired effect of many drugs used for anxiety management limiting its usage. Ayurveda recommends a bio- physical procedure to manage anxiety. *Shirodhara*, a dripping procedure is utilized as a front line therapy for anxiety in Ayurveda. Seeing the limitations of conventional biomedical management of anxiety requiring an improvement upon the existing protocols of managements, and also seeing the use of *shirodhara* for anxiety management in ayurvedic clinics, a pragmatic study to evaluate the effect of *shirodhara* in generalized anxiety disorder was done. This was a pragmatic study consisting of *shirodhara* with *ksheer bala* oil as an intervention upon generalized anxiety disorder patients. The study was conducted upon 15 patients and observations were done for six weeks. The responses observed through the changes in Hamilton Anxiety Scale were evaluated using paired t test to observe the pre-post significance.

KEYWORDS: anxiety, generalised anxiety, *shirodhara*, ksheer bala oil.

INTRODUCTION

Anxiety is understood as the state of apprehension or uneasiness arising due to the anticipation of insecurity or assault. It is pathological when it is unreasonable, exaggerated, recurrent and causing a significant psycho-physiological distress. Generalized anxiety disorder (GAD), a common variant of anxiety disorders, has 2 - 5% prevalence in general population (Baxter et al., 2013). With an increasing population and subsequently increasing socio-economic stress, incidence of anxiety is also increasing. Anxiety affects the personal performance causing a significant dip in the quality of the social - interpersonal relationship. Eventually, a patient of anxiety disorder fails to contribute optimally to the personal or societal needs. The result is a significant personal and societal direct and indirect loss.

Anxiety is a pervasive phenomenon continuing for a significant period. Current stake of therapy for anxiety disorder depends upon antidepressant drugs and Cognitive behavioral therapy (CBT). Dependency and requirement of prolonged treatment sessions are biggest limitations of the existing therapeutic options for Anxiety. Withdrawal is also a challenge once these drugs are instituted.

Ayurveda for its pro-health principles, utilizing the natural resources and healthy life measures, is emerging as a user friendly, economical, viable, and dependable treatment alternative for many physical and mental illnesses. *Samshamana* (palliation) and *Samshodhana* (elimination) constitute the two major modes of Ayurveda interventions in a disease. *Panchkarma* is a comprehensive *Samshodhana* strategy from Ayurveda, aiming at elimination of disease causing agents by various specialized means and methods. There are many allied bio-physical procedures also within the purview of *Panchkarma* as a help in treating various ailments. *Shirodhara*(oil dripping on fore head), *Shirovasti* (oil bath of scalp), *Netravasti* (oil bath of eye), *Januvasti* (oil bath of knee) are example of such procedures having their specific method of application and indication as per the classical reference of Ayurveda.

Shirodhara (*Shiro* means head and *dhara* means flow) involves gentle pouring of a medicated liquid upon the forehead. It is traditionally used to treat variety of conditions related to cognition, sleep and anxiety.

Although, existing scientific evidence regarding the therapeutic effectiveness of *shirodhara* in various traditional indications is supportive to the claims made in this regard, the strong evidences are still lacking for its use in specific clinical conditions. It is in this purview, a pragmatic study to observe the effect of *shirodhara* in patients of Generalised Anxiety disorder was carried out.

INCLUSION CRITERIA	EXCLUSION CRITERIA
• Patients with confirmed diagnosis of Generalized Anxiety Disorder as per ICD-10DCR. • Age not less than 18 years and not more than 60 years. • Informed consent from the patient showing his willingness to participate in study.	• Patient suffering from any psychiatric disorder other than GAD. • Patient suffering from any major medical illness requiring significant care. • Patient not willing to participate in study. • Patient with serious suicidal & Homicidal risk, substance or alcohol dependence, any thyroid abnormality. • Pregnant women. • Current use of Shirodhara within past two months prior to screening. • Any known allergy to the treatment components.

MATERIALS AND METHODS

Study setting

The study was conducted at Post Graduate Department of Kaya Chikitsa, JIAR college & hospital.

Study design

It was a pragmatic study where the patients were given 10 sittings of *shirodhara* in a span of 3 weeks and followed up in a treatment free period for another three weeks.

Execution of the treatment

For this study, the maximum time period of observation was six weeks. To all patients 10 sittings of *shirodhara* were given on alternate days within the first three weeks of treatment. After the first three weeks, the *shirodhara* was stopped and patients were kept under observation without any treatment.

Components	Scientific identity	Process
Ksheer	Cow's Milk	One part with ¼ part of paste, one part of oil and 4 parts of decoction
Bala	Roots of Cida Rhombifolia	Dried root was cut into small pieces and boiled with 16 times water on mild heat to be reduced to 1/8 of the initial quantity. The decoction was strained finally. Some quantity of root was made as a paste
Oil	Sesame Oil	One part oil is mixed with 1/4th part of paste, one part of milk and 4 parts of decocation boiled on mild heat till the process completes

Drug and procedure standardization

Shirodhara in the study was done with the help of *Ksheerbala* oil. The oil was prepared following the classical preparatory method of oil as is described in Ayurveda. Bala (Cida rhombifolia) roots, Cow's milk and sesame oil, the three main components of *ksheerbala* oil were procured from the local market and were verified for their genuineness. Standard *shirodhara* procedure was adopted for the execution of the therapy. In this lukewarm oil was poured on the forehead of the subjects in a lying position from a height of approximately six inches. A steady flow of oil is insured by keeping sufficient oil in a pot above the head which then flows down with the help of a cotton wick allowing the dropping of the oil on the forehead. The procedure completes in about 45 min.

RESULTS

The trial was conducted upon 17 patients who fulfilled the inclusion criteria and have given their consent for the intervention. 2 patients failed to turn to follow ups and hence eliminated from the evaluation. Data analysis was done upon rest 15 patients. The statistical analysis was done using SPSS (Statistical Package for Social Sciences) Version 15.0 statistical Analysis Software. The values were represented in Number (%) and Mean ± SD. Among 15 patients included in the analysis the mean age was 32 years. Out of 15 patients 11 were male and 4 were female.

Group	N	Min	Max	Mean	SD	Median
Base line	15	23	33	30.23	2.743	31
1st Follow up	15	16	25	21.38	2.43	21
2nd Follow up	15	18	26	21.69	2.36	21

At baseline, HAM-A scores ranged from 23 to 33 with a mean value of 30.23 and a standard deviation of 2.743. At baseline median HAM-A-score value was 31. At first follow up, HAM-A scores ranged from 16 to 25 with a mean value of 21.38 and a standard deviation of 2.43. At first follow up median HAM-A score value was 21.

At second follow up, median HAM-A score value ranged from 18 to 26 with a mean value of 21.69 and a standard

deviation of 2.36. At second follow up median HAM-A score value was 21.

The change between baseline and second follow up was 8.54 ± 2.11. Statistically, this change was significant ($p < 0.001$). Between baseline and first follow up a reduction in HAM-A-score was observed (8.85 ± 1.72) which was also significant statistically ($p < 0.001$). However, between first and second follow up intervals an increase in HAM-A score was observed but it was not significant statistically ($p = 0.104$)

DISCUSSION

Anxiety disorder is a common morbidity found as an independent or secondary condition. GAD has anxiety as the predominant feature reflecting through various physical and psychological domains.

Although there is a rising incidence and prevalence pattern of anxiety disorders in the society, there are not much evolutions in their therapeutic handlings. For most of such conditions, group of drugs having predominant effect upon serotonergic neurotransmitters are commonly recommended. Irrespective of the symptomatic relief offered by such drugs initially, these drugs also offer a dose dependent activity, dependence and rebound withdrawal symptom.

Shirodhara has shown its anti-anxiety, antihypertensive and sleep inducing effects in few studies. Physiological responses of *shirodhara* procedure are found to reduce the sympathetic tone thereby decreasing the cardiac activity and increasing α and θ wave activity in brain. This is postulated that this may causes a relaxing effect upon the recipient terminating into the induction of sleep during the treatment session. Attempts have been made to differentiate the effects of *shirodhara* with various mediums like water, decoction, oil and milk and the most pronounced effect were obtained with oil as a medium.

One recent study demonstrated the improved sleep quality in patients of GAD after shirodhara along with an ayurvedic oral formulation. This combined treatment was found effective in reorganizing the sleep architecture.

Effects of *ksheerbala* oil *shirodhara* are similar to the observations made earlier in this context. Besides sesame oils,

SN	Time interval	Mean Change	SD change	"t"	"p"
1	Baseline to first follow up	- 8.85	1.72	18.494	< 0.001
2	Baseline to second follow up	- 8.54	2.11	14.617	< 0.001
3	First to second follow up	0.31	0.63	- 1.76	0.104

the intervention compound also had milk and Bala root extract, having distinctive restorative and antioxidant properties respectively. One important observation made in the study is about the sustainable effects of *shirodhara* upon the symptoms of anxiety. As it was observed through the changes in the HAM-A score, a statistically non significant change was observed between 1st and 2nd follow up observation. As per the study protocol, the patents were given *shirodhara* till 1st follow up and were followed up without intervention for another three weeks. A minimal difference in HAM-A score between 1st and 2nd follow up is indicative that the improvements offered by *shirodhara* are stable at least for another three weeks when no other active intervention is provided.

Ayurvedic medicines and procedures are required to be identified for their additive, synergistic, complementary and adjunct roles for their possible integration to standard biomedical therapeutic options available in a given clinical conditions. Besides their independent roles, if such ayurvedic medication or procedure can prove to be complementary to standard therapy, this would be of substantial benefit as a help in reduction of the duration, adversity and cost of the therapy with an improved effectiveness of the net integrated intervention.

There are many limitations in the study which are required to be noted before net impact of this study may be comprehended. The sample size in the study is substantially small. It is obvious to note that with small sample size the perceived result may not be conclusive. The conclusions of the study are based upon a single anxiety measurement parameter (HAM-A). Although this is a standard parameter to measure anxiety level in anxiety related clinical conditions, this would have been much better if change in quality of life could also be notified. *Shirodhara* utilized in this study has its own limitations. We don't know if a *shirodhara* procedure given on everyday basis would have been better than a *shirodhara* given on alternate days or three times in a week. To make a judgment like this, specific pharmacokinetic and pharmacodynamic studies are needed to get to know that how long the impact of this procedure lasts upon the patients.

Finally, the study was done and followed up for a limited period whereas generalized anxiety disorder is a chronic phenomenon requiring a long term management strategy.

CONCLUSION

In conclusion, *Shirodhara* invited considerable attention among scientific community in recent past. The major concern of this interest is its usefulness in various neurocognitive disorders without any internal drug intake. *Shirodhara* is used routinely in ayurvedic clinics for conditions like insomnia, headache, migraine, anxiety and stress. Impacts of various mediums used in *shirodhara* are reported and maximum stress reducing effects are observed through oil as a medium. Effects of *shirodhara* are found to be equated with meditative state and a reduction in catecholamine and an increased serotonin reuptake is proposed as one mechanism of its

action. *Shirodhara* can be a good addition to existing anxiety management protocol with reduced dependency and reduced adversity but with added efficacy of the integrated protocol. More robust and long term follow up studies are however required to reach to this conclusion.

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