

Original Article

Effects of *shirodhara* in generalized anxiety disorderSanjeev Rastogi^{1,2,*}, Anriksha Baiswar¹, Anil Nischal³, Prem Swarup Srivastava⁴, Anuradha Nischal⁵¹State Ayurvedic College and Hospital, Lucknow; ²Rashtriya Ayurveda Vidyapeeth, New Delhi; ³Department of Psychiatry, KG Medical University, Lucknow; ⁴Shivalik Ayurvedic Medical College and Hospital, Ajamgarh; ⁵Department of Pharmacology, KG Medical University, Lucknow, India**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 13 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 (Rastogi, 2012). *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 forehead), *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 (Vinjamury et al., 2014; Nakanekar et al., 2015; Sriranjni, 2009), 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.

Besides *shirodhara*, anxiety is dealt in Ayurveda with *satvavajaya* (ayurvedic psychotherapy) and a few *samsamana* (palliative) measures including the use of few herbs like *Jatamansi* (*Nordostychnus jatamansi*), *Brahmi* (*Bacopa monnieri*), *Ashwagandha* (*Withania somnifera*) and *Vacha* (*Acorus calamus*). Various *ghrita* (clarified butter) preparations are also prescribed in various psychiatric conditions described in Ayurveda. Other traditional systems practiced in the world also have their own theories and approach towards anxiety. In

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Table 1. Inclusion and Exclusion Criteria for the patient selection

Inclusion Criteria	Exclusion Criteria
1. Patients with confirmed diagnosis of Generalized Anxiety Disorder as per ICD-10DCR. 2. Age not less than 18 years and not more than 60 years. 3. Resident of Lucknow and adjoining districts. 4. Informed consent from the patient showing his willingness to participate in study.	1. Patient suffering from any psychiatric disorder other than GAD. 2. Patient suffering from any major medical illness requiring significant care. 3. Patient not willing to participate in study. 4. Patient with serious suicidal & Homicidal risk, substance or alcohol dependence, any thyroid abnormality. 5. Pregnant women. 6. Current use of Shirodhara within past two months prior to screening. 7. Any known allergy to the treatment components.

traditional Chinese medicine (TCM) it is considered as a deficiency of Chi (energy) and the dominance of Yin over Yang leading to a depressive state.

MATERIALS AND METHODS

Study setting

The study was conducted at Post Graduate Department of Kaya Chikitsa, State Ayurvedic College and Hospital, Lucknow and was collaborated with Department of Psychiatry, King Georges' Medical University, Lucknow, India.

Ethical clearance

Institutional ethical clearance was granted for the conduction of the studywide IEC/AYM013/2013.

Registration to clinical trial registry of India

The study was registered to clinical trial registry of India (CTRI) with the registration number REF/2014/007145.

Study period

In the study the individual observations were made for 6 weeks. Actual study begun on 02.02.2014 and completed on 07.11.2014.

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.

Selection of subjects for the study

The subject selection was based on a strict inclusion and exclusion criteria (Table 1). Only those who came under the category of inclusion were subjected for informed consent.

Table 2. Components and preparation of *Ksheer Bala* Oil

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 1/4 th part of paste, one part of milk and 4 parts of decoction boiled on mild heat till the process completes

Those who fall under the inclusion and have given the consent have been recruited for the treatment.

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.

Parameters of evaluation

Hamilton Anxiety Rating Scale (HAM-A) (Hamilton, 1959) was the primary parameter to observe any difference of pre and post treatment responses among the patients.

Data collection:

Base line data was collected at the time of treatment allocation before the actual start of therapy. First follow up data was collected after three weeks of therapy. Second follow up data was collected after six weeks.

Data analysis

Paired t test was used for data analysis on pre and post intervention basis.

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 (Lahorkar, 2009). Bala (*Cida rhombifolia*) roots, Cow's milk and sesame oil, the three main components of *ksheerbala* oil (Table 2) 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 15 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 13 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 13 patients included in the analysis the mean age was 32 years. Out of 13 patients 11 were male and 2

Table 3. Base line, 1st Follow up and 2nd Follow up HAM-A Score

Group	N	Min	Max	Mean	SD	Median
Base line	13	23	33	30.23	2.743	31
1 st Follow up	13	16	25	21.38	2.43	21
2 nd Follow up	13	18	26	21.69	2.36	21

were female.

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 (Table 3). 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 ($p = 0.104$) (Table 2).

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 (Uebaba et al., 2008).

Shirodhara has shown its anti-anxiety, antihypertensive and sleep inducing effects in few studies (Vinjamury et al., 2014; Nakaneekar et al., 2015; Sriranjni, 2009). 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 (Uebaba et al., 2008; Xu et al., 2008). This is postulated that this may causes a relaxing effect upon the recipient terminating into the induction of sleep during the treatment session (Tokinobu et al., 2015). 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 (Tokinobu et al., 2015).

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 (Tubaki et al., 2016).

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

Table 4. Comparison of Change in HAM-A score values at different follow up intervals (Paired t-test)

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 (Dhalwal et al., 2005). 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 patients 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.

From ayurvedic perspective, for eradication of a disease, *samprapti* (pathogenesis) of the same has to be dissociated and unless it is done, a continuation of the therapy would be required to get a sustained relief in the symptoms. *Shirodhara* is a procedure requiring a clinic setup for its execution, it serves as a limitation for generalizability of this in any disease requiring a long term management.

In view of these limitations, the study meekly argues for a new therapeutic approach of combining selective serotonin reuptake inhibitors with *shirodhara* to get sustainable, safe and cost effective intervention to deal with generalized anxiety disorder.

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 (Dhuri et al., 2013; Uebaba et al., 2005). *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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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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