Research Article

Clinical Assessment of the Impact of *Shirodhara* with water Treatment in the Management of Primary Headache with associated Anxiety and Depression

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ABSTRACT

Shirodhara (dripping of fluid on forehead) is a popular ayurvedic treatment for relieving the headache and stress. *Shirodhara* induces a peaceful state of awareness that results in a dynamic psycho-somatic balance. The present study was conducted on 40 cases of primary headache for 15 days duration with an objective of clinical efficacy evaluation of *Shirodhara with water* and *Shirodhara with water* and *Ashwagandha* (*Withania somnifera*) extract orally in the management of headache along with associated anxiety and depression. The patients were randomly divided into two groups of 20 each. It was observed that the patients of group B treated with water *shirodhara* and *Ashwagandha* (*Withania somnifera*) extract (500 mg once a day) have shown significant improvement, whereas the group A treated with only *Shirodhara* with water also showed similar improvement.

Key words: *Shirodhara*, *Aswagandha*, Anxiety, Stress, Depression, Primary headache

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Introduction

Ayurveda the traditional health care wisdom of orient, throughout its classics, has projected a regulated life style to maintain the healthy state of body and mind [1-6].

Headache is one common disorder of the nervous system presented as primary and secondary headache[7]. Primary headaches are the disorders where headache and associated features occur in the absence of any obvious exogenous cause. The most common ones in the category are migraine, tension-type headache, and cluster headache. Headache often results in considerable disability and a decrease in the patient's quality of life. Secondary headaches are caused by exogenous diseases such as meningitis, intracranial hemorrhage, brain tumor, temporal arteritis and glaucoma, etc. Headache disorders impose a significant burden on sufferers including impaired quality of life and financial cost. Repetitive headache episodes, and persisting fear for the next one causes a significant disruption in the family life, social life and job. The long-term effort of coping with a chronic headache may predispose the victim to other ailments such as anxiety, stress and depression.

Migraine is the second most common cause of headache. It is largely an episodic headache and associated with certain features such as sensitivity to light, sound, or movement; nausea and vomiting. Migraine headache can precipitate following certain trigger factors, such as glare, bright lights, and sounds etc. [10-12] Tension-type headache is described as chronic headache syndrome. It is characterized by bilateral tight, band like discomfort. It is

completely without accompanying features such as nausea, vomiting, photophobia, and aggravation with movement. Cluster headache is an uncommon form of primary headache (0.1%). In this case, pain is usually deep, retro orbital, often unbearable in intensity, non fluctuating, and explosive in nature. It is typically characterized by periodicity.

In *Ayurveda*, *Shirah shula(shirah*= head, *shula* =pain) was presented as the symptom complex in cases of *Shiroroga* (diseases pertaining to head). Various types of *Shiroroga*, were described by *Charaka* and *Sushruta* in their respective classics on *Ayurveda.* [1-4].

Many forms of headaches are intractable to treatment. *Ayurveda* describes a range of pharmacological and non pharmacological procedures to treat headaches which are currently clinically practiced. Such traditional practices however needed to be validated for their safety and efficacy on scientific parameters. *Shirodhara* is one such procedure popular in ayurvedic practice. Hence this study was launched.

The *Ayurveda* texts describe four types of oleation techniques (*Murdha taila*) to deal with *shiroroga.* . These include *Shirah Abhyanga*(head massage), *Seka* (head fomentation) , *Pichu* (placing oil soaked cotton on scalp) and *Basti* (oil irrigation of scalp). On the basis of techniques employed, each one of these are proposed to have a different mode of action and effect. Beside these four classical techniques, *Shirodhara* is one special treatment widely practiced in Kerala for psychic and psychosomatic diseases. *Shirodhara* is the process in which a liquid (medicated oil, milk, buttermilk or herbal decoction) is poured in a continuous stream on the forehead in a prescribed manner. Depending upon the its constituents, *Dhara* may be recalled variously such as *Takradhara(dhara* with buttermilk), *Kshiradhara(dhara* with milk), *Tailadhara(dhara* with oil), *Kvathadhara(dhara* with decoction) and *Jaladhara(dhara* with water). This procedure induces a relaxation response, which results in a dynamic psycho-somatic balance. *Shirodhara* is an effective traditional *Panchakarma* procedure for balancing the *Doshas* and to improve the synchronised functioning of the brain, there by relieving the headaches. [9-11]

As per the general experiences at Ayurvedic clinics, *Shirodhara* is found useful in stress and psychosomatic disorders, psychiatric disorders, neurological disorders (called as *Vata Vyadhi* including facial palsy and loss of memory). This is also noticed that *Shirodhara* may not be indicated in patients, who do not tolerate it well or those having *Kaphaja Vikaras* (a cluster of disease dominated by features like heaviness, lethargy and sleepiness).

Material and Methods

For the present study patients from *Kayachikitsa* (Ayurvedic Medicine) OPD of University Hospital, Institute of Medical Sciences, Banaras Hindu University Varanasi (India) were screened and selected on the basis of predefined inclusion and exclusion criteria(Table 1) .

Table 1. Inclusion and Exclusion Criteria used in the study

Inclusion Criteria

- Patients of both sex, between the age of 16 to 60 years
- Repeated attacks of headache lasting 4-72 hours in patients with a normal physical examination, without any other reasonable cause for the headache.
- Chronic headache.(persisting for more than a year)
- Headache which is pressing, tightening/stretching in nature.
- Headache induced in stressful situations.
- Patients having primary headache.
- Hamilton Depression Rating Scale (HDRS) score 20 or Higher [12]
- Hamilton Anxiety Rating Scale (HARS) score 15 or Higher [13]
- Patient those had all of three = Headache + Anxiety + Depression

Exclusion Criteria

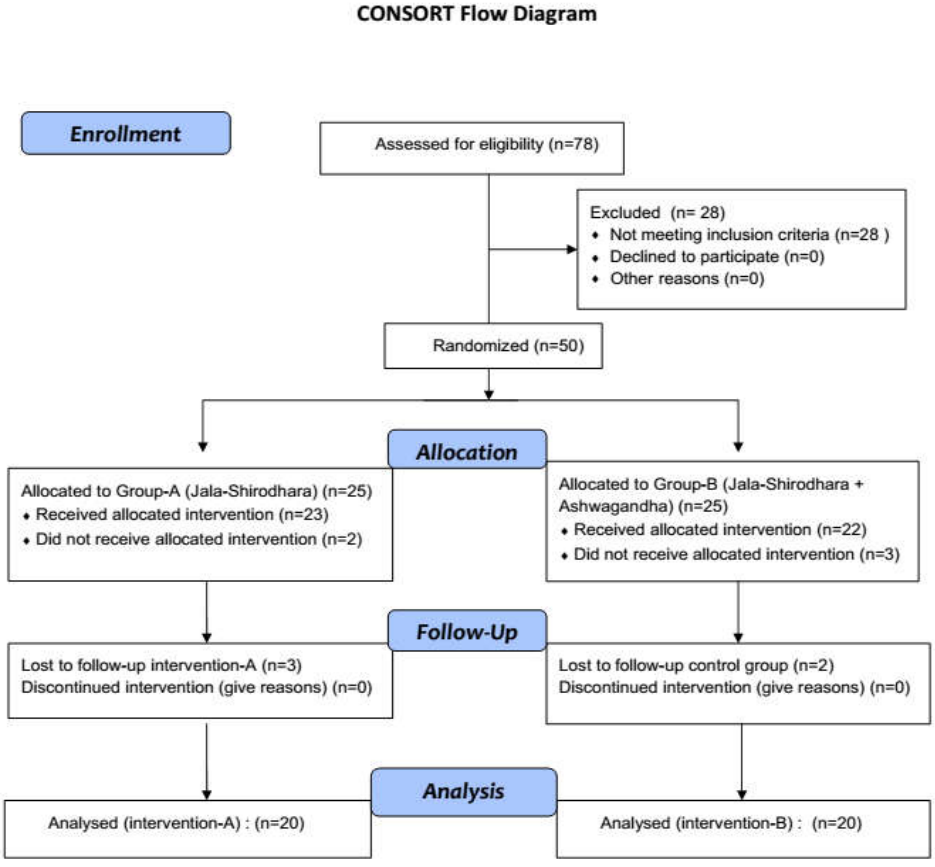
- Patients of age below 16 years and more than 60 years.
- Associated with any systemic disorders affecting the presentation.
- Patients with any ENT and eyes disorder.
- Pregnant and lactating mothers.
- Secondary headache arising due to other causes such as meningitis, intracranial tumor, cervical spondylosis etc.
- Patients with severe hypertension.

The sample size calculation was done on the basis of estimates of mean and SD for before and after treatment observed in previous researches [14] on 2 important parameters namely, Hamilton Depression Rating Scale and Hamilton Anxiety Rating Scale. The level of significance was taken as 0.05 and power of the test as 0.90. The higher sample size on these 2 variables was obtained as 20. Further, taking 20% as non-response or loss to follow-up, the required sample size became 25 in each group.

A random allocation sequence had been generated by computer and accordingly the cases were then randomly allocated into two groups of equal size. Purpose is to compare rather to see if both joined together (as additive) have any additional benefit.

Thus, 50 chosen cases were randomly allocated into 2 groups of 25 each. However, 10 cases 5 cases from each group did not participate in the study or dropped out. So the final data analysis included 40 participants (Study Flow Diagram) .

Study Flow Diagram



Group A – 20 Patients – Treated with *Shirodhara* with water as the single therapy for 15 days.

Group B – 20 Patients - Treated with *Shirodhara* with water along with an *Ashwagandha (Withania somnifera*) extract in the dose of 500 mg once a day for 15 days.

Outcome measures

- Headache, its intensity and frequency
- Visual analogue scale test for headache
- Hamilton Depression Rating Score
- Hamilton Anxiety Rating Score

Hamilton Depression Rating Scale (HDRS) also abbreviated to HAM-D, is a multiple choice questionnaire that clinicians may use to rate the severity of a patient's major depression. The questionnaire rates the severity of symptoms observed in depression such as low mood, insomnia, agitation, anxiety and weight loss. This instrument is presently one of the most commonly used scales for rating depression in medical research. Hamilton Anxiety Rating Scale (HARS) also abbreviated to HAM-A is widely used interview scale to measure the severity of a patient's anxiety, based on 14 parameters. It takes 15-20 minutes to complete the interview and scoring. Each item is simply given a 5-point score - 0 (not present) to 4 (severe). There is limited empirical research establishing cutoff scores for categories of severity on the HDRS and HARS. For the present study the optimal HDRS score ranges were: mild depression = 8-16; moderate depression = 17-23 and severe depression e" 24.[15] Similarly, the optimal HARS score ranges were: mild anxiety = 8-14; moderate = 15-23; severe e" 24 (scores d" 7 were considered to represent no/minimal depression/anxiety).[16]

Visual analog scale is a measure of pain intensity. It is a continuous scale comprised of usually 10 cm or 100 mm length anchored by "no pain" (score of 0) and "pain as bad as it could be" or "worst imaginable pain" (score of 100 on 100-mm scale). As regards Visual Analogue Scale (VAS) test the cut-off points were determined on a 100 mm VAS as: no pain 0-2 mm, mild pain 2-17 mm, moderate pain 17-47 mm, severe pain 47-77 mm, very severe pain 77-96 mm.[17]

Statistical Analysis

The basic characteristics of cases according to groups were shown by number and percent and chi square test was applied for inter-group comparison. Wherever, expected frequency came less than 5, chi square had been calculated after suitably pooling the cell frequencies. The observed scores of VAS, HDRS and HARS were shown according to cutoff as no, mild, moderate or severe. Mann-Whitney test was applied for inter-group comparison whereas; Wilcoxon Signed Ranks test was applied for intra-group comparison (before and after treatment). The p value less than 0.05 was considered as statistically significant.

Procedure of *Shirodhara*

Cristalmind *Shirodhara* machine was used for *Shirodhara* in present study.[18-19] It is a fully automatic *Shirodhara* machine which maintains the temperature selected (36.5 / to 38.5°C) and circulation of water and stops after completion of the session (Figure 1-3). The *Shirodhara* was done every morning for 45 minutes for 15 days in a clean, ventilated and quiet therapy room under direct supervision of the first author (GKS) to ensure the procedural perfectness.. After the completion of the session, the head of the patient was wiped with a cotton towel to be dried. Patient was advised to avoid mental excitement, physical exertion, sexual contact and exposure to cold, sun, wind, smoke or dust etc. during the treatment period.

Result and Observation

Base line features of enrolled patients revealed that 75% cases of both the groups were aged between 20-60 years though, the proportion of females was higher in Group-1 comparing to Group-2. The percentage belonging to lower socio-economic class was higher in both the groups. All cases were identified as of *Dwandwaja Prakriti* (dual type of constitution) where the percentage of *Pitta-Kapha* was higher in Group-1 while in Group-2 the higher percentage was of *Vata-Pitta* (Table-1). This difference was however non-significant. The difference between group A and B was not statistically significant before treatment for grades of VAS test (p=0.053), HDRS (p=0.157) and HARS (p=0.333).

Values of Visual Analogue Scale test for headache was noted before and after treatment for both the groups. In Group-A 100% cases initially had moderate or severe to very severe pain whereas, after treatment only 15% had moderate or severe to very severe pain. In Group-B 75% cases had severe and 25% had very severe pain before treatment whereas, after treatment the percentage of no pain and mild pain was 20 and 70. The intra group comparison showed highly statistically significant difference in severity grades of depression after treatment as compared to before treatment in both the groups. After the completion of therapeutic trial there was marked improvement in the headache in both groups. The rate of improvement was slightly higher in group B i.e. mixed therapy group (*Shirodhara* and *Ashwagandha* extract 500 mg once daily). Significant improvement was also observed in group A treated with water *Shirodhara* alone. The difference between group A and B was not statistically significant after treatment. (Table-2)

Values of Hamilton Depression Rating Scale were noted before and after treatment for both the groups. In Group-A 95% cases initially had severe depression whereas, after treatment only 20% had severe depression and remaining 80% had either mild or moderate depression. In Group-B 80% cases had severe and 20% had moderate depression before treatment whereas, after treatment the percentage of no and mild depression was 20 and 70. The intra group comparison showed highly statistically significant difference in severity grades after treatment as compared to before treatment in both the groups. After the completion of therapeutic trial there was significant improvement in the depression scores in both groups. The rate of improvement was slightly higher in group B i.e. mixed therapy group (*Shirodhara* and *Ashwagandha* extract 500 mg once daily). Significant improvement was also observed in Group-A treated with water *Shirodhara* alone. Further, the difference between group A and B after treatment was found statistically significant. (Table-3)

Values of Hamilton Anxiety Rating Scale were noted before and after treatment for both the groups. In Group-A 100% cases initially had either moderate or severe anxiety whereas, after treatment 25% had no anxiety and 50% had moderate and only 20 had severe anxiety. In Group-B 30% cases had severe and 70% had moderate anxiety before treatment whereas, after treatment the percentage of no and mild anxiety was 40 and 55. The intra group comparison showed highly statistically significant difference in severity grades of anxiety after treatment as compared to before treatment in both the groups. After the completion of therapeutic trial there was marked improvement in the anxiety scores in both groups. The rate of improvement was higher in group B i.e. mixed therapy group (*Shirodhara* and *Ashwagandha* extract 500 mg once daily). Significant improvement was also observed in group A treated with *Shirodhara* alone. The difference between group A and B was not statistically significant after treatment. (Table-4)

Discussion

The effect of treatment seen in these cases after the *Shirodhara* treatment as described above seems largely a *Dhara* effect and may not completely be attributed to its pharmacological or medicinal effect. The *Dhara* is proposed to produce a biophysical impact in the form of micro-vibration of the skull. The impact may be transmitted

to the brain tissue helping in resynchronization of neurons. Another important component underlying the mechanism of *Dhara* effect could be its relaxation response, and the meditative action which might be responsible for the positive therapeutic responses. The meditation effect in *Shirodhara* is obtained by focalization of the patient's attention (without effort) on a single focus, the agreeable sensation on the forehead, thus inducing a deep mental and physical relaxation state. However, till date there is no real robust evidence to substantiate this mechanism. The work of Uebaba et al (2005) has explained the effect of *Shirodhara* on cardiovascular functions.[18] Some workers in the past have suggested that use of water in place of oil for *Shirodhara* may be equally effective.[19] Further studies are required to substantiate the efficacy studies by reasonable mechanism studies on the action of *Dhara*.

The present study revealed a significant trend of clinical remission of headache (measured by visual analogue scale), and decrease in the level of anxiety and depression as measured by Hamilton Rating Scale.

It is imperative to mention that the *Shirodhara* treatment classically utilizes some or the other kind of medicated oil besides butter milk, milk and herbal decoctions as the medium of *dhara* impact. While in the present study the water was used in an uniformly regulated manner for temperature and pressure instead of any other recommended medium . It was hypothesized that that the effect of *Dhara* may not actually be the medicinal effect of oil but is a biophysical impact on scalp created by the medium. The very purpose of the present study therefore is to generate scientific evidence in favour of water *shirodhara* being it highly economical comparing to other mediums like oil , milk and butter milk .

This alternative option of the *Dhara* material was considered in order to make the treatment more cost effective and user friendly. This choice was also motivated by the past experience of the investigators .[20-22] However, it cannot be overemphasized that traditionally oil is used in *Dhara* treatment because oil *Dhara* is much more smooth and well-formed as compared to water *Dhara*. What medicinal components of oil might be offering in the net *dhara* effect is still a question to be solved. Until proved for its distinct pharmacotherapeutic effects, use of expensive medicated oils for *Dhara* treatment may not a real value. In future , this is highly recommendable to undertake a well controlled comparative study between oil *Dhara* and water *Dhara*. In addition, *Shirodhara* treatment if used in combination with *Yoga* and *Medhya Rasayan* (herbs having distinct nootropic and cognitive effects) therapy of Ayurveda the overall result may be enhanced.[23-25]

It is important to indicate that because of the gender differences between the groups, the results might have been affected after assignment. Drop-outs is also a limitation though, this has been anticipated in the beginning therefore, the sample size was taken 25 which actually required 20 in each group for statistically significant results.

Conclusion

The present study conducted on 40 cases of primary headache for 15 days duration showed significant trend of reduction in degree of headache, level of anxiety and depression and level of stress. The procedure of treatment was simple, cost effective and patient friendly. The therapeutic effect is most likely to be biophysical in nature instead of only pharmacological action i.e. the therapeutic effect of *Dhara* is not merely medicinal effect of the liquid used but , it is also to a significant extent due to biophysical *Dhara* effect.

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Table-1: Distribution of cases according to different characteristics

Characteristics		No. and (%) of cases		Between the Group Comparison
		Group A	Group B	
Age (in years)	0-20	1 (5)	4 (20)	p = 0.056
	21-40	7 (35)	10 (50)	
	41-60	8 (40)	5 (25)	
	61-80	4 (20)	1 (5)	
Sex	Male	6 (30)	15 (75)	p = 0.004
	Female	14 (70)	5 (25)	
Marital Status	Married	14 (70)	11 (55)	p = 0.327
	Unmarried	6 (30)	9 (45)	
Occupation	Employed	1 (5)	4 (20)	p = 0.029
	Student	5 (25)	8 (40)	
	Farmer	3 (15)	5 (25)	
	Housewife	11 (55)	3 (15)	
Socio Economic Status	Lower	12 (60)	10 (50)	p = 0.525
	Middle	4 (20)	9 (45)	
	Upper	4 (20)	1 (5)	
Diet	Veg	14 (70)	7 (35)	p = 0.026
	Mixed	6 (30)	13 (65)	
Prakriti	Vata-Pitta	5 (25)	9 (45)	p = 0.410
	Pitta-Kapha	10 (50)	7 (35)	
	Vata-Kapha	5 (25)	4 (20)	
Religion	Hindu	20 (100)	20 (100)	-

Table-2: Visual Analogue Scale (VAS)

Group	VAS Grade	Number and (Percent) of Cases		Within the Group Comparison (Wilcoxon Signed Rank Test) BT v/s AT
		Before Treatment	After Treatment	
Group – A (Shirodhara with water)	No Pain	00 (00)	01 (05)	p < 0.001
	Mild Pain	00 (00)	16 (80)	
	Moderate Pain	02 (10)	02 (10)	
	Severe Pain	17 (85)	01 (05)	
	Very Severe Pain	01 (05)	00 (00)	
Group – B (Shirodhara with water + Ashwagandha)	No Pain	00 (00)	04 (20)	p < 0.001
	Mild Pain	00 (00)	14 (70)	
	Moderate Pain	00 (00)	00 (00)	
	Severe Pain	15 (75)	02 (10)	
	Very Severe Pain	05 (25)	00 (00)	
Between the Group Comparison Mann-Whitney Test (Gr.A v/s Gr.B)		p = 0.053	p = 0.240	

Table-3: Hamilton Depression Rating Scale (HDRS)

Group	HDRS Grade	Number and (Percent) of Cases		Within the Group Comparison (Wilcoxon Signed Rank Test) BT v/s AT
		Before Treatment	After Treatment	
Group – A (*Shirodhara* with water)	No Depression	00 (00)	00 (00)	p < 0.001
	Mild Depression	00 (00)	07 (35)	
	Moderate Depression	01 (05)	09 (45)	
	Severe Depression	19 (95)	04 (20)	
Group – B (*Shirodhara* with water + *Ashwagandha*)	No Depression	00 (00)	04 (20)	p < 0.001
	Mild Depression	00 (00)	14 (70)	
	Moderate Depression	04 (20)	02 (10)	
	Severe Depression	16 (80)	00 (00)	
Between the Group Comparison Mann-Whitney Test (Gr.A v/s Gr.B)		p = 0.157	p < 0.001	

Table-4: Hamilton Anxiety Rating Scale (HARS)

Group	HARS Grade	Number and (Percent) of Cases		Within the Group Comparison (Wilcoxon Signed Rank Test)
		Before Treatment	After Treatment	
Group – A (*Shirodhara* with water)	No Anxiety	00 (00)	05 (25)	$p < 0.001$
	Mild Anxiety	00 (00)	10 (50)	
	Moderate Anxiety	11 (55)	04 (20)	
	Severe Anxiety	09 (45)	01 (05)	
Group – B (*Shirodhara* with water + *Ashwagandha*)	No Anxiety	00 (00)	08 (40)	$p < 0.001$
	Mild Anxiety	00 (00)	11 (55)	
	Moderate Anxiety	14 (70)	01 (05)	
	Severe Anxiety	06 (30)	00 (00)	
Between the Group Comparison Mann-Whitney Test (Gr.A v/s Gr.B)		$p = 0.333$	$p = 0.113$	

Figure -1 Cristalmind *Jala-Shirodhara* Machine

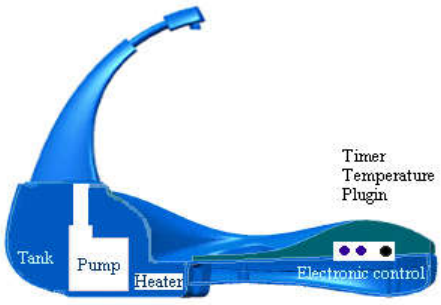

Figure-2 Operating parts of the machine

Figure-3 *Jala-Shirodhara* in operation