

An open randomized clinical study to evolve the usefulness of the predefined ayurvedic medicines in the management of tension type of headache

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Abstract

"Sirahsoola" is the leading disorder of the present practice. In modern science, Sirahsoola may be correlated with tension type of headache, in which mild to moderate pain, which is usually bilateral, with involvement of the temporal regions and it may be scattered, extend from the head to the back of the neck, and/or to the temporomandibular joint. Nasya, Shirolepa etc. are various suggested regimens in Ayurvedic texts for the treatment of Sirahsoola. 30 patients having classical signs and symptoms of Vataja sirahsoola as per Ayurvedic texts were selected. Trial medicines selected on the principles of Ayurveda were prescribed and the results were assessed before and after treatment. After therapy administration, the overall effect of therapy showed that twenty three patients (77%) were marked improvement, followed by seven patients (23%) were moderate improvement, and no any patient was unchanged or complete remission. No any adverse drug reaction was found during whole study. The results and observation which were received from this study it can be concluded that is showing better results in Vataja sirahsoola.

Keywords: sirahsoola, vataja sirahsoola, tension type of headache, shirolepa

Introduction

"Sirahsoola" is the leading disorder of the present practice. Sirahsoola, which have formed from the Sirah and Sula, in general Sirah means head and Sula means pain. Head is greatly valued by ancient Indians and prime importance given for the protection from the diseases. Charaka in his Charaka Samhita has given, in living being, the head is the most important place among the vital organs of the body and it is the seat for life and all the sense organs. All the ancient Acharyas have described the Sirahsoola as a separate disease. In Context of Siroroga, Acharya Sushruta given 11 diseases^[1], though Acharya vagbhata included kapala roga in this^[2]. Shirahsoola develop due to various etiological factors i.e. Expose to smoke, sun and snowfall, indulging in water sports, excessive sleep and asleep during night time, excessive sweating etc^[3].

According to Astanga hrudaya, the signs & symptoms of Vataja Sirahsoola are Pricking pain in the temples, Pain in the of brows, Pain in the forehead, Giddiness or head reels, Pulsation in head, Pain in ears, Noise in ears, Eyes feel as plucked out, Photophobia or Intolerance to light, Running in the nose, Rigidity of the lower jaw and shoulders. Sirahsoola get relief of pain without any reason occasionally and reduction in its severity by massaging, anointing with oil and fomentation^[4]. There is general line of treatment described in the classics for all types of Sirahsoola. Snehana, Swedana, Pariseka, Shirolepa, Nasya etc. Ac Shirovasti etc are various suggested regimens in Ayurvedic texts for the treatment of Vataja sirahsoola. According to Yogaratnakara, shirovasthi is beneficial in this^[5]. After screening of Chikitsa of 'Sirahsoola', we selected Rasnadhī chūrṇa external application and Triphala guggulu internally.

Aim and Objectives of the study

To assess the effect of Shirolepa with Rasnadhī chūrṇa in management of Sirahsoola and Triphala guggulu internal and study Vataja sirahsoola with reference to Tension type of headache from Ayurveda and modern system of medicine.

Clinical study

Study Population

Patients attending the OPD of Shalakya Tantra Department provided material for clinical study. 30 patients were selected irrespective of their sex, religion, occupation etc. fulfilling the criteria of selection and eligibility for the study.

Criteria for selection of patients

Patients are having classical signs and symptoms of Vataja sirahsoola (Tension type of headache) as per Ayurvedic and modern texts. Patients are excluded who suffering from serious systemic diseases, having severe or complicated headache due to brain lesions, other type of headache like Migraine etc. Mentally weak patients or in co-operative patients and those who are not ready to accept the treatment.

Materials and Methods

Patients were examined clinically. Thoroughly clinical assessment of signs and symptoms was performed. Record and follow-up of all the patients included in the treatment was documented. Written consent was taken from the patient. The efficacy of the therapy was assessed on subjective criteria. Rasnadhī chūrṇa and Triphala guggulu are prescribed for the treatment. Advised to the patient Rasnadhī chūrṇa is applied with water on forehead and temples region. Triphala guggulu is given with water 3 times a day. Patients were recalled for evaluation of condition on 5th, 7th and 15th day of treatment.

Criteria for Assessment

Grading of parameters taken for assessment

- 0- No complaint.
- 1- Sometime/ rarely having complaint.
- 2- Intermittent complaint which is relieved by remedy.
- 3- Continuous having complaint which is not relieved by remedy.

Overall Assessment of Therapy

The overall assessment was calculated on the basis of average improvement in the percentage relief of symptom score. The total effect of Therapy was marked as follows:

- 1. Complete Remission: 100% relief in signs and symptoms.
- 2. Marked improvement: 75% relief to 99% relief in signs and symptoms.
- 3. Moderate improvement: 50% up to 74% relief in signs and symptoms.

- 4. Mild improvement: 25% up to 49% relief in signs and symptoms.
- 5. No improvement: Below 25% relief in signs and symptoms.

Statistical Analysis

The information gathered on the basis of observation made about various parameters, was subjected to statistical analysis in term of Mean, Standard Deviation (SD) and Standard Error (SE). The data were analyzed by paired t’test, at p<0.05, p<0.01, and p<0.001. The obtained results was interpreted as, Non significant: p>0.05, Significant: p<0.05, Highly significant: p<0.01, P<0.001

Observation and Results

In the present study the demographic data is tabulated, which is being presented here in following table.

Table 1: Distribution of patients

Criteria		Number of patients	%
Age	16-20	4	13.33
	21-30	7	23.33
	31-40	8	26.66
	41-50	6	20
	51-60	5	16.66
Sex	Male	14	46.66
	Female	16	53.33
Religion	Hindu	14	46.66
	Christian	7	23.33
	Muslim	9	30
Marital status	Married	21	70
	Unmarried	9	30
Occupation	Student	3	10
	House wife	10	33.3
	Service	8	26.66
	Business	4	13.33
	Labour	5	16.66
Nature of diet	Vegetarian	11	36.67
	Mixed	19	63.33
Chronicity of disease	Up to 6 months	4	13.3
	6 months to 1 year	9	30
	1 year to 1 1/2 year	6	20
	1 1/2 year to 2 year	6	20
	More than 2 year	5	16.66

From above table it was observed that maximum 16 (53.33 %) patients were female and 14 (46.66 %) patients were male. It was observed that maximum number of patients 14 (46.6%) were Hindu, 9 (30 %) were Muslim and 7(23%) were Christian. This is because the hospital is situated in Hindu population area. So there is no any relation of distribution of disease with religion. Among registered cases 21(70%) patients were married. 10 (33.3%) were house wives, 8(26.66 %) patients were in service, 5 (16.67 %) were labour 4(13.33 %) patients were doing business, and 3(10 %) were students. The duration of disease are 6 months to 1 years in maximum 9(30%) of patients, Although in 6(20%) patients the duration of disease up to 1 year to 1 ½ year and 1 ½ to 2 year, 5 (16.66%) the duration of disease is more than 2 yrs and 4 (13.33%) patients duration up to 6 months. 19 (63.33%) patients belonged to mixed group and 11 (36.67%) patients were vegetarian. This shows that the disease is somewhat more prominent in non-vegetarian patients.

Table 2: Chief complaints wise distribution of Patients

S. No.	Chief complaints	No. of patients	%
1.	Pricking pain in the temples	27	90
2.	Pain in the eye brows	30	100
3.	Pain in the forehead	30	100
4.	Giddiness or head reels	26	86.6
5.	Pulsation in head	30	100
6.	Pain in ears	10	33.33
7.	Noise in ears	26	86.67
8.	Eyes feel as plucked out	27	90
9.	Photophobia or Intolerance to light	30	100
10.	Running in the nose	21	70
11.	Rigidity of the lower jaw and shoulders	21	70

In the present study, Pain in the forehead, Pain in the eye brows, Pulsation in head, Photophobia were found as chief complaint in 100% of patients, while pricking pain in the temples, Eyes feel as plucked out were found in 90% patients,

Running in the nose and Rigidity of the lower jaw and shoulders in 70% patients, Noise in ears in 86.67% patients, Giddiness in 86.66% patients and Pain in ears in 36.6 % patients.

Effect of Therapy

During the treatment patients were followed up after certain interval. The effect of therapy on symptoms is being presented here in following tables.

Table 3: Effect of the treatment on sign and Symptoms

S.N	Symptoms	Mean Grade Score		%of relief
		BT	AT	
1	Pricking pain in the temples	65	9	86.15
2	Pain in the of brows	74	23	68.91
3	Pain in the forehead	68	17	75
4	Giddiness or head reels	41	0	100
5	Pulsation in head	70	13	81.42
6	Pain in ears	18	8	55.55
7	Noise in ears	52	4	92.30
8	Eyes feel as plucked out	64	12	81.25
9	Photophobia or Intolerance to light	75	13	82.66
10	Running in the nose	36	2	94.44
11	Rigidity of the lower jaw and shoulders	41	13	68.29

Improvement in the symptom of Giddiness was 100%, Running in the nose was in 94.44%, Noise in ears 92.30%, Pricking pain in the temples was 86.15%, Photophobia or Intolerance to light was 82.66%, Pulsation in head was

81.42%, Eyes feel as plucked out was 81.25%, Pain in the forehead was 75%, Pain in the of brows was 68.91%, Rigidity of the lower jaw and shoulders was 68.29%, Pain in the of brows was 68.91%, and Pain in ears was 55.55%.

Table 4: Statistical analysis

S. No	Symptoms	Mean Score		%of relief	SD ±	SE ±	t	P
		BT	AT					
1.	Pricking pain in the temples	2.16	0.3	86.15	1.04	0.19	9.81	< .001
2.	Pain in the of brows	2.46	0.76	68.91	0.70	0.12	13.25	< .001
3.	Pain in the forehead	2.26	0.56	75	0.59	0.10	15.62	< .001
4.	Giddiness or head reels	1.36	0	100	0.71	0.13	10.41	< .001
5.	Pulsation in head	2.33	0.43	81.42	0.71	0.12	14.61	< .001
6.	Pain in ears	0.6	0.26	55.55	0.66	0.12	2.76	< .02
7.	Noise in ears	1.73	0.13	92.30	1.00	0.18	8.73	< .001
8.	Eyes feel as plucked out	2.13	0.4	81.25	0.58	0.10	16.27	< .001
9.	Photophobia or Intolerance to light	2.5	0.43	82.66	0.69	0.12	16.36	< .001
10.	Running in the nose	1.2	0.06	94.44	0.93	0.17	6.62	< .001
11.	Rigidity of the lower jaw and shoulders	1.36	0.43	68.29	0.78	0.14	6.51	< .001

The result of Rasnadh churna lepa and Triphala guggulu has been found highly significant (p< .001) in all the symptoms except Pain in ears (p< .02).

Overall effect of therapy

After therapy administration, the overall effect of therapy showed that twenty three patients (77%) were marked improvement, followed by seven patients (23%) were moderate improvement, and no any patient was unchanged or complete remission. No any adverse drug reaction was found during whole study. The results and observation which were received from this study it can be concluded that is showing better results in Vataja sirahsoola.

Table 5: Overall Effect of Therapy

Improvement	Patients	Percentage
Marked improvement	23	77
Moderate improvement	7	23
Unchanged	0	0

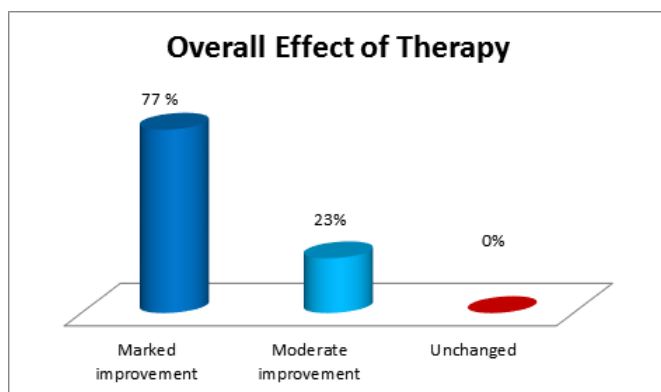


Fig 1: Overall Effect of Therapy

Discussion

Acharya Sushruta has described “Vataja shirahsoola” under the heading of Shiroroga. Acharya Sushruta has described 11 types of Shiroroga. The signs and symptoms of Vataja shirahsoola somehow resembles with Tension type of

Headache. Most headaches that are usually encountered are classified as functional headaches including migraine and tension-type headaches (tension headaches, muscle contraction headaches) [6]. Kaplan & Sadock (1995) have reported that amongst all types of headaches 82% patients are suffering from tension headache [7]. Other terms no longer in use include “psychogenic headaches” and “stress headaches” [8].

If the muscles continue to contract for a long time despite a decreased blood supply, pain substances such as lactate, pyruvic acid etc. are released. Pain occurs when these substances stimulate the nerves. Then a sensation of dull ache occurs at the sites of muscle attachment and ligaments where peripheral nerves are densely distributed. With tension-type headache, the pain occurs at the insertion of the posterior neck muscles in the occipital area. At the same time, the pain radiates across the sides of the head or the retroorbital areas; thus, the pain is also felt around these areas [9].

Tension-type headaches are more likely to occur in women. The headaches are characteristically bilateral, with a tightening or band-like sensation in the frontotemporal region around the head spreading to the occipital region or trapezius muscles. The onset is gradual, whereas the quality is dull, nonthrobbing, and constant, sometimes lasting for weeks. The cephalgia is triggered or exacerbated by stress or anxiety in most patients. Treatment of tension-type headaches uses nonpharmacologic and medical therapy. Most patients that suffer tension-type headache will respond to analgesics, such as aspirin or NSAIDs [10].

As mentioned earlier all these above mentioned symptoms are caused mainly due to vitiation of Vata. In the present study Rasnadhī chūrṇa lepa and Triphala guggulu are used for systemic treatment of Vataja Sirahsoola. Rasnadhī chūrṇa contains Rasna, Aswagandha, Devadaru, Katuka, Sarjarasa, Kushta, Vacha, Gairika, Nisa, Yashti, Bala, Mustha, Trikatu, Chirubilwa, Hingu, Balaka, Ushira, Samudra Phena, Chandana, Agarū, Tintrika dala sira. It is used in Bhrama, Murcha, Sannipata Roga, Sirastoda, Pratisyaya [11]. Triphala guggulu contains Amalaki, hareetaki, vibheetaki, pippali and guggulu [12]. Ingredients of Rasnadhī chūrṇa and Triphala guggulu are easily available and having Kapha Vatahara Property and provided better relief in almost all the symptoms because their Dravyas have Katu-tikta rasa, Laghu-tikshna-sukshma guna, Deepana, pachana property and Katu Vipaka [13].

Total 30 patients were registered for this study. These were randomly selected for the assessments of results the symptoms which are mentioned in Astanga hrudaya were adopted. Patient got some relief in first visit and felt better in further visits. For statistical analysis to make these criteria more objective, an effort has been made to give scores to all subjective criteria. Further all the scores of symptoms have been combined to assess the overall effect of therapy. Assigning the score depending upon their severity did the assessments of signs & symptoms regarding improvement. After therapy administration, the overall effect of therapy showed that twenty three patients (77%) were marked improvement, followed by seven patients (23%) were moderate improvement, and no any patient was unchanged or complete remission. No any adverse drug reaction was found during whole study. The result has been found highly

significant ($p < .001$) in all the symptoms except Pain in ears ($p < .02$). It is showing that better results in Vataja sirahsoola.

Conclusion

It can be concluded from the study the results and observation which were received from this study it can be concluded that Rasnadhī chūrṇa lepa and triphala guggulu is showing better results in Vataja sirahsoola. No patient reported any adverse effect of the treatment. The complete course of the treatment has improved the feeling of wellbeing and health status of the patients.

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