CLINICAL EVALUATION OF ANTI-FATIGUE EFFECT OF SHRAMAHARA MAHAKASHAYA IN SHRAMA VIS-À-VIS GENERAL FATIGUE.

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Abstract:

Ayurveda is said to be '*Shashvatha Vijnana*' as it includes all the basic principles/concepts related to health and disease which will be applicable for all the time. There are some unique concepts in terms of practical applicability among which classification of *Aushadha Dravya* in Charaka Samhita is one. *Aushadha Dravya*, the integral part of *Chikithsa* has been classified in various ways in Charaka Samhita that, 10 drugs performing one similar *Karma* are grouped and termed them as *Mahakashaya*. One such *Mahakashaya* is *Shramahara Mahakashaya*. *Shrama* is "*Bahvayasakritam Kashtam*" i.e. exhaustion or tiredness following excessive physical work. *Shrama* holds equal with the concept of Fatigue of contemporary science, which is defined as the condition characterized by a state of exhaustion or generalized weakness with a pronounced inability to find sufficient energy to accomplish daily activities. There a study was conducted to assess the efficacy of Shramahara Mahakashaya in Shrama i.e. general Fatigue. **Methods**: Design: open-labelled non-comparative, prospective with pre and post assessment, single-arm, single centred clinical study. Intervention: 50 subjects with complaints of Fatigue approaching OPD & IPD of GAMC Mysuru were included in the study. **Results**: study was shown to be both clinically and statistically highly significant with '*p*' value 0.001. **Conclusion**: Shramahara Mahakashaya in the form of Sharkara Kalpana is effective in treating the general fatigue.

Key words: Shrama, Fatigue, Shramahara Mahakashaya, Anti-Fatigue action, Anti-oxidant action, Chalder Fatigue Scale.

Introduction:

Shrama is "*Vyayamadina Shranthathvam*"[1] i.e. exhaustion or tiredness following excessive physical work. *Shrama* holds equal with the concept of Fatigue of contemporary science, which is defined as the condition characterized by a state of exhaustion or generalized weakness with a pronounced inability to find sufficient energy to accomplish daily activities[2]. Fatigue is increasingly identified as a complex, multi-factorial disorder with physical and psychological dimensions. Subjects suffering from fatigue are found to have a higher risk for low productivity and efficiency as they are having problems with starting things, problems with concentration, thinking and memory. Low productivity and low efficiency in-turn cause stressful family and work atmosphere and impacts overall quality of life.

Shramahara Mahakashaya[3] described by Acharya *Charaka in Shadvirechana Shatashritiya Adhyaya of Suthra Sthana,* is meant for the pacification of Shrama. by considering the properties of the drugs mentioned under *Shramahara Mahakashaya,* clinical study has been conducted to assess the combined effect in Shrama vis-à-vis general Fatigue. Shrama is mentioned as symptom in Ayurveda classics as such there is no *Samprapti* or pathogenesis described for the same. Hence for diagnosis and assessment, Chalder Fatigue Scale was used which is reliable and proved to be a valid scale in assessing Fatigue.

Objectives:

Evaluation of effect of Shramahara Mahakashaya in the subjects of Shrama (General Fatigue)

Materials and Method:

Ethical approval and registration of trial:

Approval from IEC has was taken before commencement of trial and consent was also taken from all the participants of the study. Ethical Clearance No. – IRC-EC/SS(5)2019-20

CTRI registration:

Trial has been registered in Clinical Trial Registry of India. Reference No. - CTRI/2021/05/033321

Selection criteria:

50 subjects were recruited for the study from the OPD & IPD, with respect to age (20-40 years) and irrespective of gender, caste, religion and socio-economic status. Sampling was done through simple random sampling method and statistical analysis was done by applying Paired sample t test and Chi square test.

Administration of Drug:

Shramahara Mahakashaya (Cha.Su.4/16) in the form of Sharkara Kalpana was given for intervention for 15 days with pre & post assessment.

Diagnostic Criteria:

- ✓ Criteria fulfilling Chalder Fatigue Scale (Based on Scoring)
- ▪ Mild (3-11)
- ▪ Moderate (12-22)
- ▪ Severe Fatigue (23-33)
- ✓ Spontaneous reported complaints of tiredness on little physical work among the presenting complaints.

Inclusion Criteria:

- ✓ Subjects of age group 20-40 years, irrespective of gender, socio-economic status.
- ✓ Subjects fulfilling diagnostic criteria.

Exclusion Criteria:

- ✓ Subjects suffering from chronic systemic disorders and subjects on other medications which interrupt the study.
- ✓ subjects who were contraindicated to take *Sharkara Kalpanas*
- ✓ Pregnant women and lactating mother.

Assessment criteria:

'Chalder fatigue scale'[5]
Assessment was done on 0th day and 16th day of study.

Scale contains following questions:

1 Do you have problems with tiredness?
2 Do you need rest more?
3 Do you feel sleepy or drowsy?
4 Do you have problems with starting things?
5 Do you lack energy?
6 Do you have less strength in muscles?
7 Do you feel week?
8 Do you have difficulties in concentrating?
9 Do you make slips of the tongue while speaking?
10 Do you find more difficult to find the right word?
11 How is your memory?

Scoring method:

Question: 1-10

Less than usual – 0

Not more than usual – 1

More than usual – 2

Much more than usual – 3

Question 11:

Better than usual – 0

No worse than usual – 1

Worse than usual – 2

More worse than usual – 3

Properties of Shramahara Mahakashaya Dravya[4]:

Dravya	Doshaghnatha	Karmukatha	Pharmacological activities
Draksha (Vitis vinifera L)	Vata-Pitta Shamana	Brumhama, Vrushya, Chakshushya, Swarya, Ruchiprada	anti-oxidant, antibacterial, anticancer, anti-inflammatory, antidiabetec and cardioprotective activities
Kharjura (Phoenix sylvestrees Roxb)	Vata-Pitta Shamana	Brumhana, Vrushya, Ruchikara, Hrudya, Tarpana, Pushtikara, Shukrada, Balya	antioxidant, anti-inflammatory, gastroprotective, hepatoprotective, nephroprotective, anticancer, immunostimulant activities
Priyala (Buchanamia lanzan Spreug)	Vata-Pitta Shamana	Vrushya, Hrudya, Brumhana	antioxidant, antifungal, antimicrobial, anti-ulcer, hepatoprotective
Badara (*Zizyphus jujube* Lam)	Vata-Pitta Shamana	Hrudya, Swedya, Rechana, Bhedana, Shukrala, Brumhana, Sthauryakara	anxiolytic, antioxidant, anticancer, antimicrobial, anti-inflammatory, anti-allergy, cognitive, wound healing

Dadima (*Punica granatum* Linn)	Tridoshaghna	Hrudya, Tarpana, Shukrala, Grahi, Medhya, Balya, Dipana, Ruchya	Antioxidant, anti-inflammatory, anticarcinogenic, antiatherogenic, antiglycemic, anticancer
Phalgu (*Ficus carica* Linn)	Kapha-Pitta Shamana	Tarpana, Brumhana	antioxidant, hepato-protective, anticancer, anti-inflammatory, hypolipidemic, hypoglycemic activity
Parushaka (Grewia asiatica Linn)	Vata-Pitta Shamana	Brumhana, Hrudya	Antioxidant, analgesic, anti-inflammatory activity, Immuno-modulatary effect, prevent body weight loss, Radical scavenging activity, antihyperglycemic
Ikshu (*Saccharum officinarum* Linn)	Vata-Pitta Shamana	Balya, Vrushya, Mutrala, Shukrashodhana	antioxidant activity, cholesterol-lowering properties, diuretic, analgesic
Yava (*Hordeum vulgare* Linn)	Kapha-Pitta Shamana	Lekhana, Medhya, Agnidipana, Swarya, Balya, Varnya, Sthairykarana	Anti-hyperglycemic, vascular protective, reduces cholesterol
Shashtika (*Oryza sativa* Linn)	Tridoshaghna	Grahi, Balya, Ruchya, Swarya, Vrushya, Varnya, Brumhana, Mutrala, Shukrala, Chakshushya, Vahnipushti	Antioxidant, anti-inflammatory, anti-microbial, hepatoprotective, anti-hyperlipidemia

Observations:

Maximum i.e. 64% subjects belonging 30-40 years age group, 60% subjects were Female. 90% subjects were Hindu, 96% subjects were literate, 96% subjects were belonging urban area, 20% subjects were Housewives and 20% subjects were belonging to other occupation, 74% subjects were married, 80% were not having history of Covid-19, 16(32%) subjects were having *Rasakshaya*, 36(72%) subjects were habituated to mixed type of A*hara*. 72% subjects were having *Madhyama Koshta* , 39(78%) subjects were

having disturbed sleep, 64% subjects were habituated to Tea/Coffee, 62% subjects were doing Physical work, 23(46%) subjects were doing Excess work and 17(34%) subjects were having *Vata-Pitta* Prakruthi.

Results:

Sl No.	Question	Response		Frequency	Percentage	'*p*'
01	Do you have problems with tiredness?	0	BT	0	0%	0.001
			AT	16	32%	
		1	BT	5	10%	
			AT	22	44%	
		2	BT	25	50%	
			AT	11	22%	
		3	BT	22	44%	
			AT	1	2%	
02	Do you need rest more?	0	BT	1	2%	0.001
			AT	29	58%	
		1	BT	7	14%	
			AT	15	30%	
		2	BT	22	44%	
			AT	6	12%	
		3	BT	20	40%	
			AT	0	0%	
03	Do you feel sleepy or drowsy?	0	BT	8	16%	0.001
			AT	42	84%	
		1	BT	5	10%	
			AT	7	7%	
		2	BT	16	32%	
			AT	1	2%	
		3	BT	21	42%	
			AT	0	0%	
04	Do you have problems with starting things	0	BT	11	22%	0.001
			AT	23	46%	
		1	BT	4	8%	
			AT	12	24%	
		2	BT	13	26%	
			AT	14	28%	

		3	BT	22	44%	
			AT	1	2%	
05	Do you lack energy?	0	BT	1	2%	
			AT	12	24%	
		1	BT	5	10%	
			AT	27	54%	
		2	BT	19	38%	
			AT	9	18%	
		3	BT	25	50%	
			AT	2	4%	
06	Do you have less strength in muscles?	0	BT	3	6%	0.001
			AT	10	20%	
		1	BT	6	12%	
			AT	24	48%	
		2	BT	17	34%	
			AT	14	28%	
		3	BT	24	48%	
			AT	2	4%	
07	Do you feel week?	0	BT	2	4%	0.001
			AT	28	56%	
		1	BT	7	14%	
			AT	18	36%	
		2	BT	19	38%	
			AT	4	8%	
		3	BT	22	44%	
			AT	0	0%	
08	Do you have difficulties in concentrating?	0	BT	13	26%	0.001
			AT	28	56%	
		1	BT	11	22%	
			AT	14	28%	
		2	BT	15	30%	
			AT	9	18%	
		3	BT	11	22%	
			AT	1	2%	
09	Do you make slips of the tongue while speaking?	0	BT	30	60%	0.296
			AT	35	70%	
		1	BT	11	22%	

			AT	12	24%	
		2	BT	8	16%	
			AT	3	6%	
		3	BT	1	2%	
			AT	0	0%	
10	Do you find more difficult to find the right word?	0	BT	32	64%	0.394
			AT	35	70%	
		1	BT	7	14%	
			AT	9	18%	
		2	BT	9	18%	
			AT	6	12%	
		3	BT	2	4%	
			AT	0	0%	
11	How is your memory?	0	BT	11	22%	0.005
			AT	16	32%	
		1	BT	15	30%	
			AT	21	42%	
		2	BT	13	26%	
			AT	13	26%	
		3	BT	11	22%	
			AT	0	0%	

Discussion:

Action of combined effect of Shramahara Mahakashaya on each factor of Chalder Fatigue scale is as follows:

Due to *Vata Shamana*, *Tarpana*, *Balya*, *Vrushya*, *Pushtikara Karma*[3], present interventional drug might have reduced the tiredness in subjects. All 10 drugs are anti-oxidants and most of them are anti-inflammatory[4] in nature. This will does radical scavenging action and thus there was reduced tiredness after intervention.

Reduced problems with fatigue will reduce the need of rest. *Vata Prashamana*, *Tarpana*, *Pushti* and *Sthairyakara Karma* of *Shramahara Mahakashaya Dravya* enhance one's capacity of working without any interruptions. Thus there was reduction in need of rest.

Most frequent feedback given by subjects of present study was 'they were getting better sleep in the night'. Getting proper sleep in the night will reduce feeling of sleepy or drowsy during day time. This might be due to *Vata-Pitta Shamana* (which include *Anidra* and *Alpanidra* among their *Nanathmaja Vikara* respectively along with *Preenana*, *Indriyaprasadana* so on *Karma* and also due to anxiolytic, neural and

central analgesic activities of the drugs by which proper sleep was there during night time and reduce the extent of tiredness which is the cause for getting drowsy in daytime and thus it has reduced the incidence of daytime sleepiness or drowsiness.

Madhura Rasa and *Madhura* Vipaka of *Shramahara Mahakashaya Dravya*, does *Vatashamana*, *Shadindriya Prasadana, Sthirikarana* and facilitates normal functioning of *Vatadosha*. Thus there will be proper *Cheshta Pravartna, Prayathna, Uthsaha* and motivation towards the work and thus there was reduced problems with starting the things after intervention.

Balya, *Sthairyakara*, *Brumhana*, *Tarpana* and *Vrushya Karma* of *Dravya* will enhance the *Sharira Bala* and due to nutritional component and anti-hypoglycemic activity energy level will be maintained and therefore there was reduced lack of energy after the intervention.

Vata-Pitta Shamana and Agnideepana facilitates proper digestion and *Tarpana*, *Brumhana Karma* will help to nourish *Dhatu* and thus *Mamsadhatu* also get nourished. As all the drugs were having nutritional components, that will also play major role in the nourishment of tissues and thus the strength of muscles might have increased.

By *Vata-Pitta Shamana* and *Balya*, *Ashubalakara*, *Sthairyakara*, *Pushtikara*, *Indriya Prasadana, Medhya* and such other *Karma* exhibited by the combination of *Shramahara Mahakashaya Dravya* might have helped to combat the low energy and thus providing strength to the body. In the same way, *Vata Shamana* will help to regain the motivation by establishing *Prakrutha Karma* of *Vata*. Thus, it has reduced the feeling of weakness.

Again *Vataprashamana* is evident in normalizing the problems related with concentration. *Anvasthita chitta* or *Chitta Chanchalathva* can be tackled by bringing the *Vatadosha* into its *Prakrutha Avastha*. Also, *Dadima* and *Yava* are having *Medhya* property, *Madhurarasa* is *Indriya Prasadakara* and *Amla* is *Indriya Drudeekara* which enhances the positive aspects of *Manas*. Not only these aspects, providing the strength, maintaining proper energy levels will result in healthy status of Mind also as a famous proverb says "sound mind is in a sound body".

Most of the subjects were not having the problem of tongue slips in present study. Though clinical significance was observed, it was not considerable when compared to the result of other factors. As *Vak Pravrutthi* includes complex mechanism, present intervention might not be effective.

Only 9 subjects out of 50 were complained of difficulty in finding the right word while speaking. Because of less incidence of this particular aspect, it is difficult to draw the conclusion about the effect of intervention.

Shramahara Mahakashaya Dravya does *Vatashamana*, and *Dadima* and *Yava* are having *Medhya* property. This may be the reason that there was improvement in the memory.

Conclusion:

The intervention was effective in these components of Chalder Fatigue Scale- Relieving the tiredness, Reducing the frequency and period of rest, Reducing the daytime sleepiness or drowsiness, Improving the motivation, Energy levels and muscle strength, Reducing the feeling of weakness and Improving concentration and memory. The intervention was not effective in these components of Chalder Fatigue Scale- Reducing the tongue slips while speaking and in reducing the difficulty in finding the right word. As a whole, the intervention was statistically highly significant with 'p' value 0.001.

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