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A COMPARATIVE STUDY ON MALE AND FEMALE TAGARA (VALERIANAJATA-MANSIJONES) TO EVALUATE THEIR EFFECT IN SHIROROGA W.S.R. TO ARDHAVBHEDAKA

Gupta Chandni[1], Palsra Pankaj [2], Sharma Navneet[3], UpadhayayaAshwani[4]

[1]Lecturer, [2] A.M.O. at Distt.Kullu (H.P.), M.D, [3]Reader, [4]Professor & H.O.D.,
P.G. Dept. of Dravyaguna, R.G.G.P.G.AYU. College, Paprola, Himachal Pradesh, India

Email: kaurachandni17@gmail.com

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ABSTRACT

If the human body is considered as a tree, the head is considered as root of this tree. Our *Acharayas* have mentioned *Shira* as supreme among all three vital organs. *Shira* is considered as *uttamanga* that is where *prana* (vital breathe) of living beings and also all the sense organs are located and which is best of all organs.Therefore any disease of *Shira* region is important. Thus it becomes a primary responsibility of each of us to take care of our head with utmost priority. *Ardhavbhedaka* is also such type of disease in which mortality rate is almost zero but patient always remains in great suffering. It is one of the most common types of headaches which affect more than 10% of the general population. This can be correlated with problem Migraine of the modern time. Despite recent progress, drug therapy for prevention and treatment for such headaches remain unsatisfactory for many patients. *Tagara* has been described in *Vedana Sthapana Dravyas* by *Acharya* P.V. Sharma and used for *Shiroroga* by *KaidevNighantu* because of its *ushnaveerya* which pacifies *vatadosha*. *Shirahshool* in *Ardhavbhedaka* is mainly due to *vata* predominant *doshas*, hence both male and female *Tagara* are selected to evaluate their effect as *Vatashamakadravyas* w.s.r. to its *vednashamaka* effect. Present paper attempts to provide comparative information on the efficacy of male and female *Tagara* to evaluate their effect on *shiroroga* w.s.r. to *Ardhavbhedaka.*

Keywords: *Uttamanga*, *Shiroroga*, male and female *Tagara*.

INTRODUCTION

Shira is considered as *Uttamanga* i.e that where vital breathe of living beings and also all the sense organs are located, and which is the best of allorgans[1]. Acharaya Vagbhatta has compared the human being with a tree which is having its roots at the top and branches below and defined head as a site where all senses along with the vital breath *(prana)* reside[2],[3]. Thus it is supreme of all organs hence, it requires prime protection. Head hold the sense faculties and the channels like Sun hold its rays[4]. As regards the vital organs are located in the trunk, *Shira* is considered as one of the three

important vital organs i.e. *Shira, Vasti, Hridaya* since the existence of the body is dependent upon them[5]. Injury to *Shira* may lead to death of the person[6] or it may lead to rigidity of the sides of the neck, facial paralysis, agitation of the eyes, stupefaction, and constricting pain in the head, loss of movement, cough, dyspnoea, trismus, numbness, sluttering speech, closed condition of the eye-lids, twitching of the cheeks, yawning fits, ptyalism, aphasia and facial asymmetry[7]. In the classical texts, the word *Shiroroga* has been used to denote painful conditions of head, only thus commentator *Chakrapani* has not included other diseases of head such as *Khalitya, Arunshika* etc. in *Shiroroga*[8]. Acharaya Charaka has described five types of *Shiroroga* in *Sutrasthana*[9] and four others in *Sidhisthana*[10]. Acharaya Sushruta has classified eleven types of *Shiroroga*[11] .Acharya Vagbhatta has enumerated ten types of painful states of head along with nine other disorders of scalp (*Kapalgata*)[12]. *Ardhavbhedaka* is the disease of the head in which a violent and excruciating pain of a piercing or aching nature is felt in one half of the cranium. It makes the patient feel giddy, and either follows no distinct periodicity or re occurs at a regular interval of ten days or a fortnight. This is called the *Ardhavabhedaka* and is due to the concerted action of the three *doshas*[13]*or by vatakapha*[11]. Thus, *Ardhavbhedaka*, a *Sadhya* type of *Shiroroga* can be best managed with the treatment having *Ushna, Snigdha, Vatahara* or *Vata-Kaphahara* properties. It is one of the most common types of headaches which affect more than 10% of the general population. This can be correlated with problem Migraine of the modern time. Despite recent progress, drug therapy for prevention and treatment for such headaches remain unsatisfactory for many patients. *Tagara* is very important religious and medicinal plant used in folk and *Ayurvedic* system. It is used in *havan* and worships because of its antimicrobial properties and is helpful in psychological disorders. *Tagara* has been described in *Shiroroga* treatment by different Acharyas. *Tagara* has been described in *Vedana Sthapana Dravyas*[14]by *Acharya* P.V. Sharma and used for *Shiroroga* by *KaidevNighantu*[15]. *Shirahshoola* in *Ardhavbhedaka* is mainly due to *vata* predominant *doshas*, hence both male and female *Tagara* are selected to evaluate their effect as *Vatashamakadravyas* w.s.r. to its *Vednashamaka* effect, so the present study has been undertaken to evaluate pharmaco-therapeutic effects of male and female plants separately.

AIMS AND OBJECTIVES

1. To record data on safety and efficacy of the drug.
2. To record data on any adverse effect of the drug.
3. To evaluate the *Vedanashamaka* effect of *Tagara* on *Ardhavbhedaka.*

MATERIAL AND METHODS

ETHICAL CLEARANCE:

The proposed clinical study was presented in the form of a synopsis in front of the Institutional, R.G.G.P.G Ayurvedic Hospital, Paprola, Ethical Committee. The clinical trial was started after the approval from the Chairman of Ethics committee.

STUDY DESIGN:

The therapeutic protocol in the present study includes 20 patients in two different groups, selected from O.P.D. of R.G.G.P.G. Ayurvedic Hospital, Paprola. The patients found to be suffering from *Ardhavbhedaka* and consenting to participate in the drug trial were selected and divided randomly in two groups. Clinical study was carried out under direct supervision of Guide and Co-guides, by taking an account of inclusion and exclusion criteria. Detailed history was taken according to the proforma prepared for the study incorporating all

the relevant points from both Ayurvedic and modern views.

Selection of Patients:

1. **Inclusion criteria**

- Patients willing for trial.
- Patients presenting with the cardinal signs and symptoms of *Ardhavbhedaka.*
- Patients of age group>18 years.

2. **Exclusion criteria**

- Patients not willing for trial.
- Patients not fulfilling inclusion criteria.
- Patients with history of any chronic illness associated with *Shirovedana.*
- Patients with headache due to optic or sinus origin.

Consent of Patients:

All the patients selected for trial were explained the nature of study and their consent was obtained on the proforma before inclusion in the study.

Laboratory Investigations

Estimation of Hb%, TLC, DLC, ESR, were carried out on the volunteers to rule out any organic and systemic disease.

Grouping of Patients:

The diagnosed patients were divided into following two groups:

Group -I

Tagaramoola Churna-1(Rhizome of male plant)- Orally

Group -II

Tagaramoola Churna-2(Rhizome of female plant)- Orally

Dose of formulation [16]

Group-I

Tagaramoola Churna-1 - 3g (1g TID) in divided doses

Anupana - Jala

Group-II

Tagaramoola Churna-2- 3g (1g TID) in divided doses

Anupana - Jala

Duration of trial - 15 days

Follow up

Two follow-ups with drug at the duration of 1 week and one follow-up after one week of completion of trial

Statistical Analysis:

The obtained data was analysed statistically and expressed in terms of mean score before treatment (BT), after treatment (AT), difference of mean (BT-AT), standard deviation (SD) and standard error (SE).

Overall percentage improvement of each patient was calculated by the following formula:

$$\frac{\textbf{Total BT - Total AT}}{\textbf{Total BT}} \times \mathbf{100}$$

- Students paired t test was applied at $p>0.05$, $p<0.05$, $p<0.01$, $p<0.001$, to observe significance of results obtained after treatment. The results were considered significant or insignificant depending upon value of p.
- Highly significant - $p<0.001$
- Moderately significant - $p<0.01$
- Significant - $p<0.05$
- Insignificant - $p>0.05$

Criteria for Assessment:-

The improvement in patients was assessed on the basis of relief in the signs and symptoms of the disease. For this purpose main signs and symptoms were given score according to their severity. The details of the score adopted for the main signs and symptoms in this study are as follows:

1. **Intensity of Headache**

- 0 = No headache.
- 1 = Mild headache, patient is aware only if he/she pay attention to it.

- 2 = Moderate headache, can ignore at times.
- 3 = Severe headache, can't ignore but he/she can do his/her usual activities.
- 4 = Excruciating headache, cannot do anything.

2. Frequency of Headache: Assessed in term of days

- 0 = Nil
- 1 = > 15 days
- 2 = <15 days
- 3 = <10 days
- 4 = < 5 days

3. Duration of Headache: (Assessed in term of hours/day)

- 0 = Nil
- 1 = 1-3 hours/day
- 2 = 3-6 hours/day
- 3 = 6-12 hours/day
- 4 = More than 12 hours/day

4. Nausea:

- 0 = Nil
- 1 = Occasionally
- 2 = Moderate, but does not disturb the routine work
- 3 = Severe, disturbing routine work
- 4 = Severe enough, small amount of fluid re-gurgitating from Mouth

5. Vomiting:

- 0 = Nil
- 1 = Only if headache does not subside
- 2 = Vomiting 1-2 times
- 3 = Vomiting 2-3 times
- 4 = Forced to take medicine to stop vomiting

6. Giddiness

- 0 = Nil
- 1 = Feeling of giddiness
- 2 = Patient feels as if everything is revolving
- 3 = Revolving signs + black outs
- 4 = Unconsciousness

Analysis of Data and Presentation:

The data from clinical study was assessed by using suitable statistical methods and presented in the form of dissertation.

Criteria for Final Assessment of Results

The total effect of therapy was assessed in five groups:-

Table 1:

Cured	100% relief in signs and symptoms and no recurrence during follow up study have been considered as cured.
Marked Improvement	>75% - <100% improvement in signs and symptoms has been considered as marked improvement.
Moderately improvement	>50% - <75% improvement in signs and symptoms has been recorded as moderate improvement.
Mild improvement	>25% -<50% improvement in signs and symptoms has been considered as mild improvement.
Unchanged	upto 25% reduction in signs and symptoms was noted as unchanged.

OBSERVATIONS AND RESULTS

Observation regarding dose of drug:

In the study protocol dose of drug was kept as 3g/day i.e. 1 g TID which has been described by API. The clinical study was started with the same dose. Most of the registered patients after 2-3 days informed the problem of drowsiness and sleepiness after taking the drug. A few patients stopped taking drug at their own. It was assumed that at this dose level, the drug is causing drowsiness and sleepiness. So the dose was reduced to 2 g/day i.e. 1 g BD. The further trial was conducted on this

dose and there was no report of similar problem again.

Table 2: Distribution of Patients:-

	Group -1	Group -2	Total	%age
Registered	10	10	20	100
Completed	10	10	20	100

The study of age incidence in 20 cases of *Ardhavbhedaka* showed that maximum number of patients were found belonging to the age Group -of 20-40 years i.e. 45%, followed by 40 % in the age Group of >40 years, 65% patients were females and 35 % patients were males and the study of incidence of religion showed that 100% patients registered were Hindu. The study of educational status among the registered patients showed that, maximum patients were graduate 30%, followed by matric and senior secondary school. 20 % each, maximum patients were students 30%, Housewives 20%, followed by govt. job and farmers 15% each, 70% patients were married followed by 30% patients unmarried. The study of mental status among the registered patients, 35% patients were normal followed by 25% patients who were under category of anger and 20 % were under category of anxiety , 15% were tensed and 1 % under depression. The study of *Prakriti* showed that 45% patients were *KaphaVataj,* followed by 25% patients who were *Vataj*, 10% who were *Kaphaja and Pitta Kaphajeach and 5 % were Pittaj and VataPittaja each.* The study of *Mansikaprakriti* among the registered patients showed that, 65% patients were *Rajas* followed by 35% patients who were *Tamas.* The study of *Satmaya* among the registered patients showed that, 60% patients were of *MadhyamaSatmaya* followed by 25% patients of *HinaSatmaya* and15% of *PravaraSatmaya.* The study of *Satva* among the registered patients showed that, 65% patients were of *MadhyamaSatva* followed by 20% patients of *PravaraSatva*, 15% of *HinaSatva*. The study of *AbhyavaranShakti* among the registered patients shows 50% patients were of *MadhyamaAbhyavaranshakti* followed by 25% patients of *Hinashakti* and25% of *PravaraShakti*.

The study of *Jaranashakti* among the registered patients shows, 55% patients were of *MadhyamaJaranashakti* followed by 25% patients of *HinaJaranashakti*,35 % patients were having *Mandagni* followed by 30% patients having *Vishamagni* and 20% having*Samaagni*,15% having *Tikshanagni* . 45% patients were having *KruraKoshtha* followed by *30% of MadhyamaKoshtha* and 25% patients having *MriduKoshtha*. The study of *Vyayamashakti* among the registered patients showed that 55% patients were having *MadhyamaVyayamashakti* followed by 25% patients of *Avarashakti* and 20% having *PravaraVyayamashakti.*

RESULTS

Table 3: Effect of Male *Tagara Churna* in Group-I (paired t test)

Chief Complaints	N	Mean Score		Mean		±	±		
		BT	AT	Diff.(X)	%	S.D.	S.E.	T	P
Intensity of Pain	10	2.2	1.1	1.1	50	0.5676	0.1795	6.1279	<0.001
Frequency	10	3.2	1.3	1.9	59.37	0.56765	0.17951	10.5846	<0.001
Duration	10	3	1.3	1.7	56.66	0.67495	0.21344	7.96486	<0.001
Nausea	10	1.7	0.8	0.9	52.94	0.73786	0.23333	3.85714	<0.01
Vomiting	10	1	0.3	0.7	70	1.05935	0.335	2.08958	>0.05
Giddiness	10	0.9	0.5	0.4	44.44	0.5164	0.1633	2.44949	<0.05

The effect of Male *Tagara Churna* showed that there was statistically highly significant (p<0.001) improvement in intensity, frequency and duration of pain, Moderately significant (p<0.01) improve-

ment in nausea, significant ($p<0.05$) improvement in giddiness and Insignificant ($p>0.05$) improvement in vomiting.

Table 4: Effect of Female *Tagara Churna* in Group -II (paired t test)

Chief Complaints	N	Mean Score		Mean Diff.(X)	%	± S.D.	± S.E.	T	P
		BT	AT						
Intensity of Pain	10	3	1.6	1.4	46.667	0.5164	0.1633	8.5732	<0.001
Frequency	10	2	1.2	0.8	40	0.63246	0.2	4	<0.01
Duration	10	3.1	1.6	1.5	48.3871	0.52705	0.16667	9	<0.001
Nausea	10	0.9	0.6	0.3	33.333	0.48305	0.15275	1.96396	>0.05
Vomiting	10	0.9	0.6	0.3	33.333	0.48305	0.15275	1.96396	>0.05
Giddiness	10	0.8	0.2	0.6	75	0.69921	0.22111	2.7136	<0.05

The effect of female *Tagara Churna* showed that there was statistically highly significant ($p<0.001$) improvement in intensity and duration of pain, moderately significant ($p<0.01$) improvement in frequency, significant ($p<0.05$) improvement in giddiness and Insignificant ($p>0.05$) improvement in nausea and vomiting.

EFFECT OF BOTH THE THERAPIES

Table 5: Inter Group Comparisons over criteria of assessment (unpaired t test)

Symptoms	N	%age Relief		Diff. in %age	S.D. ±	S.E. ±	T	P
		Gr.-1	Gr.-II					
Intensity	*10*	*50*	*46.66*	*3.34*	0.542604	0.24266	1.236298	*>0.05*
Frequency	*10*	*59.37*	*40*	*19.37*	0.600929	0.268744	4.09312	*<0.001*
Duration	*10*	*56.66*	*48.38*	*8.28*	0.605532	0.270802	0.73855	*>0.05*
Nausea	*10*	*52.94*	*33.33*	*19.61*	0.623608	0.278886	2.15142	*<0.05*
Vomiting	*10*	*70*	*33.33*	*36.33*	0.823274	0.368179	1.08643	*>0.05*
Giddiness	*10*	*44.44*	*75*	*30.56*	0.61464	0.274875	0.727603	*>0.05*

1. **Intensity**: Group-I showed 3.3% more relief than Group-II, the difference was insignificant statistically at $p>0.05$ ($t=1.24$)
2. **Frequency:** Group -I showed 19.37% more relief than Group-II, the difference was statistically highly significant at $p<0.001$($t=4.09$)
3. **Duration** : Group-I showed 8.28% more relief than Group-II, the difference was insignificant statistically at $p>0.05$($t=0.74$)
4. **Nausea:** Group-I showed 19.61% more relief than Group-II, the difference was statistically significant at $p<0.05$($t=2.15$)
5. **Vomiting:** Group-I showed 36.33% more relief than Group-II, the difference was insignificant statistically at $p>0.05$ ($t=1.09$)
6. **Giddiness:** Group-II showed 30.56% more relief than Group-I, the difference was insignificant statistically at $p>0.05$ ($t=0.73$)

Table 6: Overall Effect of Therapy

RESULT	Group -I N=10	%	Group –II N=10	%
Cured	2	20	0	0
Marked Improvement	1	10	2	20
Moderately Improvement	3	30	2	20
Mild Improvement	4	40	5	50
Unchanged	0	0	1	10

The overall effect of therapy showed that in Group-I i.e. *Male TagaraChurna*40% patients had mild improvement, followed by 30% moderately improvement, 20% were Cured and10% Marked improvement.

In Group-II i.e. Female *TagaraChurna* 50% had mild improvement, followed by 20 % showed marked improvement and moderately improvement each and 10% unchanged.

Table 7: Effect of therapy on Hematological and Biochemical Profile

		N	Group-I		Group-II	
			BT	AT	BT	AT
Hb		10	11.57	11.52	11.64	11.62
TLC		10	7150	7140	7050	7100
DLC	Neu.	10	62	63	65	63
	L	10	30	30.5	31.6	31.6
	M	10	4.3	3.7	4.4	3.9
	E	10	2.1	2.2	2.7	2.6
	B	10	0	0	0	0
ESR		10	8.3	8	9	8.6

Routine blood investigations were carried out before and after the treatment but no appreciable changes were observed.

The disease of the head in which a violent and excruciating pain of a piercing or aching nature is felt in one half of the cranium which makes the patient feel giddy, and which either follows no distinct periodicity or re occurs at a regular interval of ten days or of a fortnight, is called the *Ardhavbhedaka* and is due to the concerted action of the three *doshas*.

DISCUSSION

Discussion on dose of drug

The dose of drug was reduced to 2 g/day at place of 3g/day, because this was causing drowsiness and sleepiness to patient. This shows that for *VedanaShamaka* effect 2g/day dose is sufficient. However, as described in API the drug can be used as a sedative drug in a dose of 3g/day, as drug has been described in psychosomatic disorders by different *Nighantus*.

Overall Effect of Therapy

- **Group-I:** Out of 10 patients, 2 patients were cured and 1 was markedly improved, 3 patients were moderately improved, 4 were mildly improved and no patient was unchanged.
- **Group-II:** Out of 10 patients, no patient was cured and 2 were markedly improved, 2 patients were moderately improved, 5 were mildly improved and 1 patient was unchanged.

Thus it is clear that Male *Tagara Churna* is slightly more effective in treating *Ardhavbhedaka*.

Probable Mode of Action of Tagara on *Ardhavbhedaka*.

The principle of treatment of a disease is its *SamptiVighatana* means to dismantle the *SamptiGhatakas* of the disease by the drug. On the basis of this principle the probable mode of action of the drug *Tagara* on the disease *Ardhavbhedaka* has been described as follows:

According to *Acharayas* it is *Vata-KaphajaVyadhi*. Thus, *Ardhavbhedaka*, a *Sadhya* type of *Shiroroga* can be best managed with the treatment having *Ushna, Snigdha, Vatahara* or *Vata-Kaphhara* properties.

Probable Mode of Action of *Tagara* over *Doshas:* According to *Charaka* it is *VataKaphaja* disease. *Sushruta* described it as *Tridoshaja* disease whereas according to *Vagbhatta*, it is *VataPradhana* disease and the predominant symptom is *Shirovedana*. So it is clear that in *Ardhavbhedaka* the main aim of treatment should be *Vata-Kapha Shaman*. *Tagara* is *VataShamaka* because of its *UshnaVeerya*, *SnigdhaGuna* and *KaphaShamaka* because of its *Tikta Rasa*, *UshnaVeeryaandLaghuGuna*[14,17]. So the disease was selected to evaluate the pharmacotherapeutic effect of *Tagara*.

Probable Mode of Action of *Tagara*over*Dushyas*: *Dushya* of *Ardhavbhedaka* is *Raktadhatu*. *Tagara* because of its *TiktaRasa* pacifies *Pitta dosha*, so ultimately *Rakta* gets pacified, because *Pitta* and *Rakta* are *Samangunadharmi*.[18]

Probable Mode of Action of *Tagara* over *Srotas* and *Srotodushti:* *Srotas* involved in *Ardhavbhedaka*are *Vata* and *KaphavahaSrotas*. *Tikta Rasa* of *Tagara* pacifies *Kaphadosha*, so it will remove obstruction which is due to *Kaphaavrodha*[19]. Because of *UshnaVeerya* and *SnigdhaGuna* of *Tagara* it pacifies *Vatadosha*, so clears *VatavahaSrotas*[20].

Discussion Regarding Overall Effect of Drug

The overall effect of therapy showed that in Group-I i.e. Male *TagaraChurna*40% patients had mild improvement, followed by 30% moderately improvement, 20% were Cured, 10% Marked improvement. In Group-II i.e. Female *TagaraChurna* 50% had mild improvement, followed by 20%. Marked improvement& moderately improvement each and10% unchanged.

Reason for better results of therapy in group-1 patients: In the present study the rhizome of male plant was found to be more effective then female plant rhizome. The probable reason for this variation may be concentration of phytochemicals as there was no change in the microscopic structures of both rhizomes. The quantitative analysis of phytochemicals has not been conducted in the present study. Male plant was found more potent which justifies its masculine names, mentioned in different *Nighantus*. Female plant is less effective which indicates inferiority of *PindTagara* described by *Bhavaprakasha*.[17]

Adverse effects: No adverse effect was found at present dose and duration of trial. However clinical study for long duration therapy should be conducted.

CONCLUSION

- Among *Samhitas Acharaya Charaka* and *Vagbhatta* have included it in *TiktaSkandha.*
- In most of *Nighantus, Tagara* was found to have *Tikta, Katu Rasa, Laghu* and *SnigdhaGuna, UshnaVeerya* and *KatuVipaka.*
- Classics referred to its *Tridosha Shamaka Dosha Karma* along with *Bhutnashka, Vishnashka* etc. *karma.*
- It was concluded that female plant of *Tagara* can be taken as *PindTagara*.
- Total 20 patients were taken and all of them completed trial. It was an open trial comprising of two groups.
- *Tagara Moola Churna* was given in a dose of 1g BD with water for 15 days in both groups.

- Results of therapy on symptoms were better in group-I as compared to group-II.

Scope for further study

1. Further clinical study can be conducted on general headache as a quick relief analgesic drug.
2. Large sample trial for longer duration can be conducted to know about chronic toxicity and other adverse effects of drug.
3. *Tagara*has been described by *Bhavaprakasha* as *Shoolprashamana* drug and the clinical trial on pain related to *Ardhavbhedaka* has been conducted.Further trial on other types of *Shoola* can be conducted.
4. Quantitative study of both male and female rhizomes can be conducted to view variation if any.

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