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Research Article

A COMPARATIVE CLINICAL STUDY TO EVALUATE THE EFFECT OF *SHAMANA SWEDA* FOLLOWED BY *NIRGUNDI GUGGULU* IN *VAATAKANTAKA* WITH SPECIAL REFERENCE TO CALCANEAL SPUR AMONGST FEMALE POPULATION

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ABSTRACT

Vatakantaka is characterized by the pain in the heel region and included in the *Vatavyadhi* by Acharya Sushruta. It is common in about 10% of general population. Women are twice more prevalent than men. *Vatakantaka* is mainly caused due to vitiation of *Vatadosha* and continuous pressure on the heel region. In modern parlance it can be co-related with Calcaneal spur. It is observed that Calcaneal spur is more prevalent in female due to life style postures like standing for longer period, wearing high heel shoes. Various treatment measures for the management of *Vatakantaka* are given in the classics of Ayurveda like *Sushutha Samhita, Astanga Hrudaya, Vangasen Samhita. Siravyadha, Agnikarma* and *Eranda taila pana* are the main *Chikitsa* of *Vatakantaka. Acharya Charaka* said *Vatakantaka* is *Sweda sadhya Vyadhi.* So in this present study, treatment is given with *Swedana* followed by *Shamanoushadhi.* Here 40 cases of *Vatatakantaka* vis- a -vis Calcaneal spur were divided in to two groups and subjected to *Dashamula churna pinda sweda* and *Valuka sweda* for 7 days, followed by *Nirgundi Guggulu* for 30 days. Patients showed significant results in subjective and objective parameters.

INTRODUCTION

Vatakantaka is *Vata pradhana vatavyadhi* particularly caused by walking on uneven surface or by excessive strain, which produces *Ruja* in *Khuddal pradesha*[1]. Except *Charakacharya* all *Bruhat trayi* and *Laghu trayi* have accepted *Vatakantaka* under *Vataja nanatmaja vyadhi*. But *Charakacharya* has mentioned under *Sweda sadhya vyadhi*[2]. As *Vatakantaka* is one of the *Vatavyadhi*, *Sevan* of *Mityahara, Ruksha sheeta bhojana, Ratri jagarana, Vishama chesta* etc can be considered as general *Nidana* for *Vatakantaka*. *Sushrutha* and other *Acharyas* have mentioned specific *Nidanas* like improper placement of feet on the ground while walking, excessive work, *Shrama, Ati adhva* are the reasons for the manifestation of *Vatakantaka*[3].

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Vatakara ahara sevana causes *Vishamagni* which leads to formation of vitiated *Rasa dhatu,* in turn leads to vitiation of *Asthi dhatu (Uttarottara dhatus).* Mean while *Khavaigunya* which was already existed in *Gulpha pradesha* due to *Vatakara vihara* like *Vishama chesta, Ati adhva, Shrama, Vishama padanyasta,* there will be *Vikruta, Sama rupa asthi vruddhi* takes place in *Parshni pradesha*. This *Vikruta, Samarupa asthi* do the *Peedana* of *Mamsa, Peshi, Kandara* in *Parshni pradesha.* When foot is kept on the ground with whole body weight, leads to *Kantakavat veadana* and manifests into *Vatakantaka*. Person suffering from *Vatakantaka* usually presented with painful heel in morning when first step is kept, pain during walking, pain on walking on uneven surface. Almost all the signs and symptoms of *Vatakantaka* resembles with the condition of calcaneal spur described by the modern texts. Calcaneal spur is painful condition of heel caused by long-term pressure on the plantar fascia and foot muscle. This condition requires analgesics, anti-inflammatory drugs, surgical corrections, longer hospitalization and also financial expenses. The Ayurvedic science is a treasure which has scope for non surgical modalities with less financial expenditure

as well as minimum hospitalization. *Vatakantaka* being a *Vatavyadhi*, general treatment of *Vatavyadhi* can be performed like *Snehana, Swedana, Samshodhana*. *Acharya charaka* has mentioned *Vatakantaka* under *Swedana sadhya roga*[4]. *Acharya Sushruta* told *Siravyadha* as line of treatment in *Vatakantaka*[5]. *Chakradatta* in *Vatavyadhi Chikitsa* advocates blood-letting should be done frequently or *Eranda tail* should be taken or the part should be cauterized with needles[6]. Here in this study, *Shamana Sweda* is taken to manage *Vatakantaka* by two elite procedures *Valuka Sweda* and *Dashamula Churna*[7] *Pinda Sweda* followed by *Nirgundi Guggulu*[8] as *Shamanoushadhi*.

Here in the present study an effort is made to compare the clinical efficacy of *Dashamula churna pinda sweda* and *Valuka sweda* followed by *Nirgundi Guggulu* in two different groups of minimum 20 subjects each through various observations and statistical methods.

Objectives of Study

1. To evaluate the effect of *Valuka Sweda* followed by *Nirgundi Guggulu* in management of *Vaatakantaka*.
2. To evaluate the effect of *Dashamula Churna Pinda Sweda* followed by *Nirgundi Guggulu* in management of *Vaatakantaka*.
3. To compare the combined effect of *Valuka Sweda* and *Dashamula Churna Pinda Sweda* followed by *Nirgundi Guggulu* in the management of *Vaatakantaka*

MATERIALS AND METHODS

Study design- Randomized comparative clinical study.

Study population- 40 subjects of *Vatakanataka* were incidentally selected and randomly divided in to two equal groups Group-A and Group-B

Plan of work- The entire study was designed to be conducted in three phases.

The present clinical study has been registered as a Prospective study in clinical trials registry- India (CTRI). Register number – CTRI/2019/11/022132

➢ **Phase I**

- Detailed literature review done extensively using tertiary resources, secondary resources, primary resources.
- Procure the necessary documentation- Designing of data entry form, informed consent document, patient information sheet.
- Ethical committee approval- Ethical clearance was obtained from the Institutional Ethical Committee of Ayurveda Mahavidyalaya and Hospital, Hubballi.

➢ **Phase II**

- The sample size was collected which comes under the inclusion and exclusion criteria at the time of enrolment.
- Data was collected using data entry form after explaining patient information sheet and signing informed consent.

➢ **Phase III**

- Reports were analyzed using various statistical tools.
- Reporting of results and presentation

Study Criteria

Inclusion Criteria

- Patients with the *Lakshanas* of *Vatakantaka* like pain in heel, pain on walking.
- Female patients between the age group of 30-70 years.
- Patients who were fit for *Swedana karma.*

Exclusion Criteria

- Patients suffering from fracture, dislocation of ankle joint, Post traumatic ankylosis, Rheumatoid arthritis, Gouty arthritis and any orthopedic disorders causing pain in the sole of foot except calcaneal spur.
- Pregnant and lactating women
- Subjects with uncontrolled Diabetes with complications.

Source of Data

Patient interview and patients case records which contain patient's demographic history, laboratory investigation reports and prescribed drugs.

Study Materials

Consent forms and patient's data entry form

Study Procedure

Table 1: Showing Intervention of Group A

Amapachana	*Shaddharana Churna* 5 grams twice daily before food with *Ushnodaka* for 3 days.
Swedana	*Dashamula churna pinda sweda -15-20* minutes for 7 days.
Shamanoushadhi	*Nirgundi Guggulu* 2 tabs of 250mg twice daily after food for 30 days
Anupana	*Erandadi Kwatha* 15ml
Treatment duration	55 days
Follow up	Every 15th day

Table 2: Showing Intervention of Group B

Amapachana	*Shaddharana Churna* 5gms twice daily before food with *Ushnodaka* for 3 days.
Swedana	*Valuka sweda* -15- 20 minutes for 7 days.
Shamanoushadhi	*NirgundiGuggulu* 2 tabs of 250 mg twice daily after food for 30 days
Anupana	*Erandadi Kwatha* 15ml
Treatment duration	55 days
Follow up	Every 15th day

For both the groups *Amapachana* was done with *Shaddharana churna*. Subjects of Group A received *Dashamula churna pinda sweda* where as Group B received *Valuka sweda*. *Shamanoushadhi (Nirgundi Guggulu*) and *Anupana (Erandadi kwath*) was same for both groups.

Assessment Criteria

Improvement in subjective and objective parameters of *Vatakantaka* will be assessed before and after treatment.

Subjective Parameters were Assessed by Numerical Pain Rating Scale

- Morning rise of pain
- Pain on walking
- Pain on walking after rest
- Pain on walking on uneven surface

Table 3: Showing Assessment Grading of Subjective Parameters

Severity of pain (NPRS)	Grade
0	Grade 0
1-3	Grade 1
4-6	Grade 2
7-10	Grade 3

Objective Parameters with Grading

- Tenderness

Table 4: Showing Assessment Grading of Tenderness

Parameters	**Grade**
No tenderness	Grade 0
Pain on deep Palpation	Grade 1
Pain on light palpation	Grade 2
Don't allow to touch	Grade 3

- Heel test

Table 5: Showing Assessment Grading of Tenderness

Parameters	**Grades**
No pain	Grade 0
Mild pain by Heel test	Grade 1
Moderate pain by Heel test	Grade 2
Severe pain do not allow to do Heel test	Grade 3

RESULTS

Total 42 subjects of *Vatakantaka* w.s.r. to Calcaneal spur were registered, out of which 40 subjects completed the treatment. 2 subjects dropped out in between the treatment. One subject discontinued the treatment, because she was coming from long distance, so she skipped the procedure in between. Another subject

was dropped out in between the treatment because she was unable to complete follow up. Other 40 subjects completed the treatment.

Table 6: Showing Age Wise Distribution

Age	Group A	%	Group B	%	Total	%
31-40 yrs	05	25%	08	40%	13	32.5%
41-50 yrs	08	40%	07	35%	15	37.5%
51-60 yrs	04	20%	02	10%	06	15%
61-70 yrs	03	15%	03	15%	06	15%

In Group A maximum number of subjects i.e., 8 (40%) belong to the age group 41-50 yrs and in Group B, maximum number of subjects i.e., 8 (40%) belong to the age group 31-40 yrs.

Table 7: showing Religion Wise Distribution

Religion	Group A	%	Group B	%	Total	%
Hindu	17	85%	16	80%	33	82.5%
Muslim	02	10%	02	10%	04	10%
Christian	01	05%	02	10%	03	7.5%

In Group A, maximum number of subjects i.e., 17 (85%) were Hindus, 02 (10%) were Muslims and remaining 01 (05%) was Christian.

In Group B, maximum number of subjects i.e., 16 (80%) were Hindus, 02 (10%) were Muslims and 02 (10%) were Christians

Table 8: Showing Distribution of Occupation

Occupation	Group A	%	Group B	%	Total	%
House Wife	14	70%	12	60%	26	65%
Working	06	30%	08	40%	14	35%

In Group A, maximum number of subjects i.e., 14 (70%) were House Wives and remaining 6 (30%) were working.

In Group B, maximum number of subjects i.e., 12 (60%) were House Wives and remaining 8 (40%) were working.

As per the observations made here in current study titled "A Comparative Clinical Study To Evaluate The Effect of Shamana Sweda Followed By Nirgundi Guggulu In Vatakantaka With Special Reference To Calcaneal Spur Amongst Female Population " the subjective parameters like morning rise of pain, pain on walking, pain on walking after rest, and pain on walking on uneven surface were recorded before treatment and after treatment with the help of NPRS (Numerical Pain Rating Scale). The objective parameters like tenderness and Heel test were also recorded before the treatment and after the treatment and subjected to statistical analysis within the group by applying Paired "t" test and between the group by applying Unpaired "t" test using GraphPad Prism statistical software.

Table 9: Showing Effect of therapy on Subjective and Objective parameters in Group A

Parameter	Mean		Mean diff	% improvement	S.D.	S.E.	"t"	P Value	Remarks
	B.T	A.T							
Morning rise of pain	9.050	4.200	4.850	53.59 %	0.91	0.21	23.09	<0.001	S.S
Pain on walking	8.600	3.900	4.700	54.65 %	0.85	0.19	24.73	<0.001	S.S
Pain on walking after rest	8.650	4.150	4.500	52.02%	0.97	0.22	20.45	<0.001	S.S
Pain on walking on uneven surface	8.200	3.900	4.300	52.44 %	0.71	0.16	26.87	<0.001	S.S
Tenderness	2.100	0.650	1.450	69.05 %	0.59	0.14	10.35	<0.001	S.S
Heel test	2.150	0.700	1.450	67.44 %	0.59	0.14	10.35	<0.001	S.S

*BT- Before Treatment, *AT- After Treatment, *S.D- Standard Deviation *S.E- Standard error, *S.S- Statistically Significant. Table t value at Level of Confidence 99.99% and Degree of Freedom (DF) 19 is 3.883

Table 10: Showing Effect of Therapy on Subjective and Objective parameters in Group B

Parameter	Mean		Mean diff	%improvement	S.D.	S.E.	"t"	P value	Remarks
	B.T	A.T							
Morning rise of pain	8.600	2.600	6.000	69.76 %	0.794	0.17	35.29	<0.001	S.S
Pain on walking	8.200	2.000	6.200	75.60 %	0.695	0.16	38.75	<0.001	S.S
Pain on walking after rest	8.450	2.750	5.700	67.45 %	0.801	0.18	31.67	<0.001	S.S
Pain on walking on uneven surface	7.550	1.800	5.750	76.15 %	0.716	0.16	35.93	<0.001	S.S
Tenderness	2.100	0.850	1.250	59.52 %	0.444	0.10	12.58	<0.001	S.S
Heel test	2.050	0.850	1.200	58.53 %	0.410	0.09	13.33	<0.001	S.S

The mean score of morning rise of pain in Group A, before treatment (BT) was 9.0 and after treatment was 4.2 with 53.59% improvement. And there was statistically significant (p<0.001) result with "t" value 23.09. The mean score of morning rise of pain in Group B, before treatment (BT) was 8.6 and after treatment was 2.6, with 69.76% improvement. And there was statistically significant (p< 0.001) result with "t" value 35.29

The mean score of pain on walking in Group A, before treatment (BT) was 8.6 and after treatment was 3.9, with 54.65% improvement. And there was statistically significant (p <0.001)) result with "t" value 24.73. The mean score of pain on walking in Group B, before treatment (BT) was 8.2 and after treatment was 2.0, with 75.60% improvement. There was statistically significant (p < 0.001)) result with "t" value 38.75.

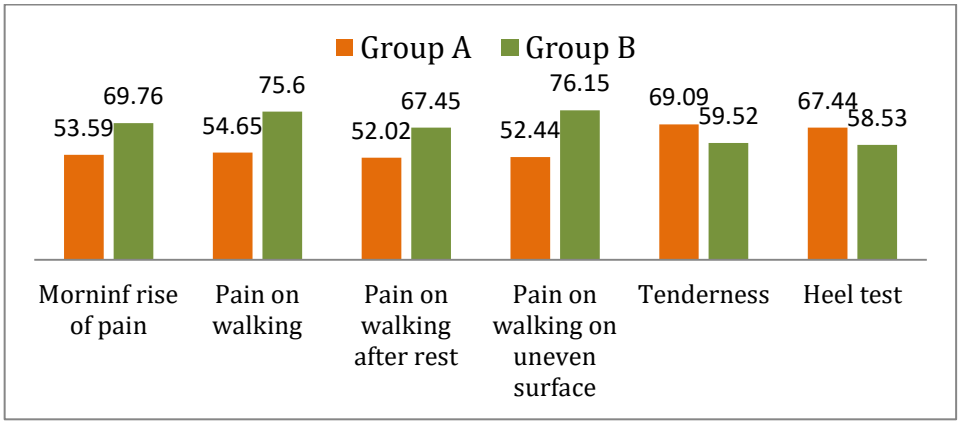
The mean score of pain on walking after rest in Group A, before treatment (BT) was 8.6 and after treatment was 4.1, with 52.02% improvement. And there was statistically significant (p<0.001) result with "t" value 20.45. The mean score of pain on walking after rest in Group B, before treatment (BT) was 8.4 and after treatment was 2.7, with 67.45% improvement. And there was statistically significant (p < 0.001)) result with "t" value 31.67

The mean score of Pain on walking on uneven surface in Group A, before treatment (BT) was 8.2 and after treatment was 3.9, with 52.44% improvement. And there was statistically significant (p <0.001) result with "t" value 26.87. The mean score of pain on walking on uneven surface in Group B, before treatment (BT) was 7.5 and after treatment was 1.8, with 76.15% improvement. And there was statistically significant (p<0.001) result with "t" value 35.93.

The mean score of Tenderness in Group A, before treatment (BT) was 2.1 and after treatment (AT) was 0.6, with 69.05% improvement. And there is statistically significant (p<0.001) result with "t" value 10.35. The mean score of tenderness in Group B, before treatment (BT) was 2.1 and after treatment was 0.8, with 59.52% improvement. And there is statistically significant (p<0.001) result with "t" value 12.58.

The mean score of Heel test in Group A, before treatment (BT) was 2.1 and after treatment was 0.7 with 67.44% improvement. And there was statistically significant (p<0.001) result with 't' value 10.35. The mean score of Heel test Group B, before treatment (BT) was 2.0 and after treatment was 0., with 58.53% improvement. And there was statistically significant (p<0.001) result with "t" value 13.33.

Graph1- Showing the effect of therapy on assessment of parameters in both Group A and Group B (in Percentage)



Comparative Efficacy of Therapy Between Group A and Group B Using Unpaired "t" Test

Let us assume that H_0= *Dashamula churna pinda sweda* followed by *Nirgundi Guggulu* is more effective than *Valuka sweda* followed by *Nirgundi Guggulu* in the management of *Vatakantaka.*

H_1= *Valuka sweda* followed by *Nirgundi Guggulu* is more effective than *Dashamula churna pinda sweda* followed by *Nirgundi Guggulu* in the management of *Vatakantaka.*

To rule out this assumption whether to accept or not, we have to have to find the "t" value using the formula Unpaired student "t" test method.

Table 11: Comparative Efficacy of Therapy Between Group A and Group B Using Unpaired "t" Test.

Assessment Parameters (N=40,D.F=38)	Group A			Group B			Unpaired t Test		
	Mean	S.D.	S.E.	Mean	S.D.	S.E	t_{cal}	P value	Remarks
Morning rise of Pain	4.8	0.91	0.21	6.0	0.77	0.17	3.73	<0.05	S.S
Pain on walking	4.7	0.85	0.19	6.2	0.68	0.16	5.37	<0.05	V.S.S
Pain on walking after rest	4.5	0.97	0.22	5.7	0.78	0.18	1.29	>0.05	N.S
Pain on walking on uneven surface	4.3	0.71	0.16	5.7	0.70	0.16	5.19	<0.05	V.S.S
Tenderness	1.45	0.59	0.14	1.2	0.43	0.10	1.01	>0.05	N.S
Heel Test	1.45	0.59	0.14	1.2	0.40	0.09	1.28	>0.05	N.S

Comparing the effect of therapy on Morning rise of pain

The mean of morning rise of pain in Group A was 4.8, SD was 0.9 and SE was 0.2. In Group B the mean of Morning rise of pain was 6.0, SD was 0.7 and SE was 0.1. The comparative efficacy of Group A with Group B showed very much statistically significant ($p<0.05$) result with t value 3.7.

Comparing the effect of therapy on Pain on walking

The mean of pain on walking in Group A was 4.7, SD was 0.8 and SE was 0.1. In Group B the mean of Pain on walking was 6.2, SD was 0.6 and SE was 0.1. The comparative efficacy of Group A with Group B showed statistically significant ($p<0.05$) result with t value 5.37.

Comparing the effect of therapy on Pain on walking after rest

The mean of pain on walking after rest in Group A was 4.5, SD was 0.9 and SE was 0.2. In Group B the mean of pain on walking after rest was 5.7, SD was 0.7and SE was 0.1. The comparative efficacy of Group A with Group B showed statistically not significant ($p>0.05$) result with t value 1.29.

Comparing the Effect of therapy on Pain on walking on uneven surface

The mean of pain on walking on uneven surface in Group A was 4.3, SD was 0.7 and SE was 0.1. In Group B the mean of pain on walking on uneven surface was 5.7, SD was 0.7 and SE was 0.1. The comparative efficacy of Group A with Group B showed very much statistically significant ($p<0.05$) result with t value 5.19.

Comparing the effect of therapy on Tenderness

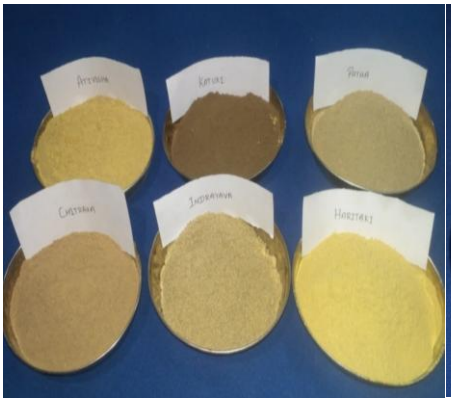
The mean of Tenderness in Group A was 1.4, SD was 0.5 and SE was 0.1. In Group B the mean of tenderness was 1.2, SD was 0.4 and SE was 0.1. The comparative efficacy of Group A with Group B showed statistically not significant ($p>0.05$) result with t value 1.01.

Comparing the effect of therapy on Heel test

The mean of Heel test in Group A was 1.4, SD was 0.5 and SE was 0.1. In Group B the mean of Heel test was 1.2, SD was 0.4 and SE was 0.09. The comparative efficacy of Group A with Group B showed statistically not significant ($p>0.05$) result with t value 1.28.

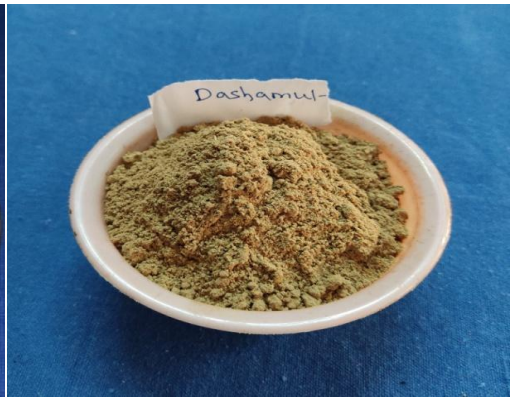
Table 12: Showing the Overall assessment of Therapy in both Group A and Group B (In percentage)

Remarks	Group A	%	Group B	%	Total	%
Marked improvement (75%-100%)	02	10%	05	25%	07	17.5%
Moderate improvement (50%-75%)	12	60%	15	75%	27	67.5%
Mild improvement (25%-50%)	06	30%	00	00%	06	15%
No improvement (below 25%)	00	00%	00	00%	00	00%



Ingredients drugs of *Shaddharana*

Vatis* of *Nirgundi Guggulu



Showing *Dashamula churna*

DISCUSSION

Vatakantaka refers to condition caused by *Vata* characterized by shooting pain i.e., *Kantakavat vedana* in the heel of the foot. As *Vatakantaka* is one of the *Vatavyadhi*, *Sevan* of *Mityahara*, *Ruksha sheeta bhojana*, *Ratri jagarana*, *Vishama chesta* etc can be considered as general *Nidana* for *Vatakantaka*. According to the life style of olden days Sushrutha and other Acharyas have mentioned specific *Nidana* like improper placement of feet on the ground while walking, excessive work (*Shrama*) *Ati adhva* (walking long distance) are the reasons for the manifestation of *Vatakantaka*. In olden days the life was difficult. There was no transportation system, no machines to work. People use to walk long distance to move from one place to other and any type of laborious work was done by the people. So *Shrama*, *Atiadhwa*, *Vishamapadasnysta* were considered the causes of *Vatakantaka*. But now in this modern era life has become very easy. There are vehicles for transportation and machines are available to do even normal routine work.

Though life has become easy, but due to unhealthy lifestyle, living healthy is a far- fetched dream for the majority of humans. In olden days women use to sit and work, but now they stand for longer period in the kitchen for cooking. Eating habits have also changed in working women. Due to work pressure they don't eat on time. They go for fast food and in turn gain weight and ends up in to obesity. Due to corporate life style women started to wear high heel shoes which is not good for the health of the feet. By these all reasons women may get *Vatakantaka* (Calcaneal spur).

Though being in modern era women in the rural area still don't wear foot ware. They walk bare foot in fields and walk long distance without using any transportation. By these *Nidana vata* gets vitiated and manifests *Vatakantaka*. These all *Nidana* can be considered as *Vyanjaka hetu* for the manifestation of *Vatakantaka*.

Vishamagni which is caused by *Vatakara ahara,* makes *Rasadhatu dushti* and *Rasadhatvagni mandya*. When *Rasadhatwgni* decreases the transformation from *Rasadhatu* to *Rakta dhatu* would be very slow and hence *Rasadhatu* increases. This applies to each *Dhatu* and *Dhatwgni.* The same effect will be seen at the level of *Asthi dhatu*. Due to *Asthi dhatwagni mandya*, there will be *Asthi dhatu vruddhi* in *Parshni pradesha.* This increased *Asthi dhatu* is *Vikruta* and *Samarupa* in nature.

Clinical presentation of patients of *Vatkantaka* reveals that it is a *Samaja vatavyadhi* because peak of pain is observed in the early morning. *Ruksha sweda (Dashamula churna pinda sweda*) is preferred here because of *Vata kapha hara, Shothahara* and *Vedanasthapaka* nature of *Dashamula*. So this proved very effective in relieving local pain and swelling. To overcome overall pain in *Vatakantaka, Nirgundi Guggulu* was choice of drug as it is *Vedana sthapaka* in nature. It can be concluded that *Vatakantaka* need not be correlated with any one particular diseases of modern science based on symptom "painful heel" or the condition in which pain is the main symptom in heel can be considered as *Vatakantaka*. In this present study *Vatakantaka* is correlated with Calcaneal spur. Calcaneal spur is a bony spike growing anteriorly from the anterior edge of a calcaneal tuberosity which causes pain in heel.

CONCLUSION

- *Vatakantaka* is a non fatal common condition found in day to day practice.
- *Vatakantaka* is common in both sexes. But women are twice more prone to get *Vatakantaka* than men. It causes severe pain especially, in the morning and during walking after long hours of rest.
- It can be co-related with Calcaneal spur in modern.
- It mainly affects the middle class women. Maximum number of subjects was housewives, who use to stand for longer period in the kitchen.

- Procedure was very simple, safe, economical, effective and done on the OPD basis. Symptomatic relief is found in all patients.
- Treatment showed statistically significant result.
- No complications were observed during the treatment.

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