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A COMPARATIVE CLINICAL STUDY ON VILLAIVER KUDINEER AND VARMAM THERAPY IN THE TREATMENT OF CERVICAL SPONDYLOSIS.

***Sugunthan S.[1], Shailaja R.[2] and Mohamed Musthafa[3]**

[1]Varmam Expert, National Institute of Siddha, Tambaram sanatorium, Chennai-47.
[2]Lecturer, Velumailu Siddha Medical College and Hospital, Sriperumpudur.
[3]Reader, Government Siddha Medical College, Arumbakkam, Chennai-106.

***Corresponding Author: Dr. Sugunthan S.**

Varmam Expert, National Institute of Siddha, Tambaram sanatorium, Chennai-47.

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ABSTRACT

Neck pain is an important cause of reduced quality of life and carries a high economic cost. This condition is increasing nowadays owing to the postural changes, poor dietary habits, the factors contributing to the degeneration of the bone. Current treatment involves usage of anti-inflammatory and analgesic drugs which often pose to hepato toxicity, nephrotoxicity and adverse drug reactions affecting gastrointestinal tract, central nervous system etc., Hence an attempt had been made to validate the drug and therapy for the management of Cervical spondylosis. The comparative study of *Villaiver kudineer, Varmam* therapy alone and combined therapy of both was done in three groups each comprising 20 patients. Group 1 received polyherbal formulation *Villaiver Kudineer*/ 60 ml B.D/ 6 weeks, Group 2 received *Varmam* therapy/ twice a week/ 6 weeks and Group 3 received both *Villaiver Kudineer* and *Varmam* therapy for 6 weeks. Among Group 1 58.21% responded, Group II 81.54% responded, Group III 82.71% responded. The result of subjective parameters had revealed that Group II and Group III have shown significant improvement in reducing all symptoms. However stimulation of *Varmam* points helped greatly to reduce sub occipital pain. The predominant symptom of CS neck pain was found to be pacified by all three treatment methodology, although combined treatment had given 90% of relief. Since the P value is highly significant ($P<0.001$) there is significant reduction of pain scale score and other gradation scale score among the patients of three groups. Varmam therapy markedly reduced the symptoms and improves the quality of life. Further combination of both *Villaiver kudineer* and *varmam therapy* has shown noteworthy improvement in assuaging the symptoms of Cervical spondylosis.

KEYWORDS: *Varmam, Villaiver Kudineer, cervical spondylosis.*

1. INTRODUCTION

Neck pain is an important cause of reduced quality of life and carries a high economic cost.[1,2] Repeated occupational trauma may contribute to the development of cervical spondylosis.[3,4,5] This condition is increasing nowadays owing to the postural changes, poor dietary habits, the factors contributing to the degeneration of the bone.

(CS) is defined as arthrosis of the posterior intervertebral joints in the cervical vertebrae[6] most typically occur at C5-C6>C6-C7>C3-C5>C7-T1. It is caused by degenerative disc disease and usually produces intermittent neck pain in middle-aged and elderly patients which usually responds to activity modification, neck immobilization, isometric exercises, medication.[7]

An increased incidence has been observed in patients who carried heavy loads on their heads or shoulders, dancers, gymnasts and in patients with spasmodic torticollis.[8] The prevalence of cervical spondylosis is similar for both sexes.[9] In males, the prevalence was 13% in the third decade, increasing to nearly 100% by age 70 years. In females, the prevalence ranged from 5% in the fourth decade to 96% in women older than 70 years.[10] Atleast 10% of the affected people develops chronic neck pain.[11]

The important crisis of this degenerative disorder is its impact on quality of life. The constant neck pain and other associated symptoms affecting the routine life, really extend this disease to pay attention to its treatment protocol. The current clinical treatments mainly include administration of non-steroidal anti-inflammatory drugs, muscle relaxants, physiotherapy, analgesics, and so on.[12] However, there is little evidence to support the efficacy of these therapies for cervical spondylosis. The usage of anti-inflammatory and analgesic drugs often pose to hepato toxicity, nephrotoxicity and adverse drug reactions affecting gastrointestinal tract, central nervous system etc.,[13] The treatment in other system does not

give complete relief. The most optimal treatment has not yet been established.[9]

Varmalogy is the special branch of Siddha Medical science still in practice in Southern parts of Tamil Nadu, especially, in Kanya Kumari and in Southern parts of Kerala. The basic principles of Varmam science explain the fundamentals of Siddha Medical system. Varmam is an extremely subtle energy flow circulating inside the body.[14] The treatment methodologies are employed in the clinical practice, especially for musculo-skeletal disorders and neurological disorders.

So, the need of the hour is to search an effective drug and therapy to treat cervical spondylosis with less or no adverse effects. Hence an attempt had been made to validate the drug and therapy for the management of Cervical spondylosis. Therefore, I have ventured to compare the efficacy of a polyherbal formulation *'Villaiver kudineer'* cited in the classical literature 'Varma odivu murivu sara soothiram 1500' for internal administration[15] and the ***Varmam therapy*** from varmam literatures to treat Cervical spondylosis.

2. MATERIALS & METHODS

2.1 ETHICAL APPROVAL & INFORMED CONSENT

Approval of the Screening committee and Institutional ethical committee (IEC NO.GSMC-CH-ME-2/016/2013) were obtained for undertaking the present study. Clinical study was registered with Clinical trials registry of India, REF No.2014/07/007248. The study design and the underlying hypothesis and the rights to withdraw from the study at any time were informed orally and in writing to all the participants.

2.2 TRIAL DESIGN

A single center randomized Comparative clinical trial to evaluate the effectiveness and safety of *Villaiver kudineer* and *Varmam* therapy for cervical spondylosis without myelopathy was undertaken in OPD of Postgraduate Department of Varmam, Puramaruthuvam and Sirappu maruthuvam, Government Siddha medical college attached with Arignar Anna Hospital for Indian Medicine and homoeopathy, Arumbakkam, chennai-106 for a period from January 2014 to January 2015. A total of 60 patients with cervical spondylosis who fulfilled the inclusion criteria were included for the study.

2.3. RECRUITMENT OF PATIENTS

Patients reporting at OPD of Arignar Anna Government Hospital of Indian Medicine, satisfying the inclusion and exclusion criteria were eligible for participation in the trial. They were included in the study with the approval of Head of the Department. They were subjected to screening test and documented using screening Proforma. Sixty patients who fulfilled the inclusion criteria were subjected to protocol comprising selection criteria, clinical assessment, Siddha assessment, laboratory investigations and treatment aspect.

2.4. CRITERIA FOR INCLUSION

Participants who fulfill the underlying criteria were considered eligible for the study

- Participants with confirmed diagnosis of cervical spondylosis without myelopathy in reference with criteria of International Classification of diseases,10th edition (ICD-10)codes
- Age: between 20 years and 60 years
- Sex: Both Male and Female
- Intensity of pain ranging from 3 to 7 points on Visual analog scale (VAS) with no varmam therapy or relative treatment in the past 1 week.
- Pain in the nape of the neck
- Cervical radiculopathy (If Spurling Test positive)
- With or without numbness in the upper limbs
- Giddiness
- Neck stiffness
- Patients willing to sign Informed consent document.

2.5. CRITERIA FOR EXCLUSION

The following conditions were excluded for the study

- History of trauma of neck/ neck surgery.
- Any neoplasm /Tuberculosis in spine/Severe osteoporosis of cervical spine.
- Congenital anomalies of spine
- Ankylosing spondylosis/ Diabetes mellitus/ Cardiac diseases
- Pregnancy and lactation
- Patients with any other serious systemic illness
- Inability to complete research questionnaires.

2.6. GROUPING OF THE PARTICIPANTS:

As and when patients fulfilling all the criteria of clinical information sheet, they were subjected to the following three groups containing 20 cases in each group. First 20 patients were subjected to group 3 treatment protocol, Second 20 patients were subjected to group 2 treatment protocol and Third 20 patients were subjected to group 1 treatment protocol as given below GROUP 1(G1): *Villaiver Kudineer*/ 60 ml B.D/ 6 weeks, GROUP 2(G2): *Varmam* therapy/ twice a week/ 6 weeks, GROUP 3(G3) : Both *Villaiver Kudineer* and *Varmam* therapy for 6 weeks.

2.7. SELECTION OF THE DRUG

The criteria for selection of drug *villaiverkudineer* was based on its claimed efficacy against Varma kayam, Enbu kayam, Narambu kayam,Vatha kayam, koluthu, kutthu and Nithirai bangam which are associated with musculo-skeletal diseases.

2.8. SOURCE OF RAW DRUGS

The required raw drugs were procured from natural habitats and some were purchased from country drug center, Chennai. The raw drugs were authenticated by the Pharmacognosist of Siddha Central Research Institute, Chennai. Then the medicine was purified and prepared in Gunapadam laboratory of Government

Siddha Medical College, Chennai-106.

2.9. LIST OF INGREDENTS

Villaiver Kudineer **(**VVK) is a Siddha polyherbal formulation from the Varmam literature Varma odivu murivu sara soothiram-1500 consists of 40 herbs namely Roots of *Aegle marmelos*, Roots of *Ficus racemosa*, Roots of *Trianthema decandra*, *Centella asiatica*, Roots of *Spermacoce hispida*, Roots of *Ricinus communis*, *Lippia nodiflora*, *Adathoda vasica*, *Solanum nigrum*, *Coleus aromaticus*, *Sida rhombifolia*, *Trichosanthes cucumerina*, *Mukia maderaspatana*, *Abrus precatorius*, *Aerva lanata*, *Scoparia dulcis*, *Solanum torvum*, *Cassia occidentalis*, *Roots of Cardiospermum halicacabum*, *Phyllanthus fraternus*, *Pergularia daemia*, *Alangium salvifolium*, *Cassytha filiformis*, *Roots of Strychnos nux-vomica*, *Picrorrhiza kurroa*, *Costus speciosus*, *Brassica nigra*, *Trachyspermum ammi*, *Roots of Piper nigrum*, *Cedrus deodara*, *Phyllanthus emblica*, *Terminalia chebula* , *Terminalia bellerica*, *Mesua ferrua*, *Crocus sativus*, *Foeniculum vulgare*, *Aquilaria agallocha*, *Acorus calamus*, *Piper longum.*

2.10. PREPARATION OF THE DRUG - VVK:

Procurement/collection of ingredients for the preparation of Villaiver kudineer. Purification of ingredients for the above was executed as per Agathiar sarakku suthi muraigal. Coarse powder mixture of the above was pocketed (70gms quantity) was dispensed.

2.11. DRUG DOSAGE

Patients who come under the treatment groups namely G1 and G3 were handed over a medicine packet and instructed to prepare decoction (kudineer) and take 60 ml bid daily as oral administration.

2.12. KUDINEER PREPARATION METHOD

Approximately 5gms were added to 240 ml of portable water and boiled to reduce into one fourth and take orally when it is lukewarm.

2.13. VARMAM INTERVENTION

Patients falling under G2 and G3 received Varmam treatment. Varmam point stimulation was done at a frequency of two sessions per week and total of twelve sessions for six weeks. After six weeks of Varmam treatment, patients were followed for further six weeks without supervision. At post treatment period 8, 10, 12 weeks the patients were called through telephone to ascertain the recurrence of neck pain.

Varmam manipulation was performed on the following points listed in the table1.

1	VARMAM POINTS	ANATOMICAL LOCATION
1.	Pidari kalam [15,16,17]	Mid of the sub occipital protuberance.
2.	Saramudichu varmam[15,16,17, 18]	It is located at the back in the cervical prominence, at the C7-T1 junction
3.	Kakkattai Kalam [15,17,19,20,21,22,23,24,25,26]	It is located in the supraclavicular fossa
4.	Kavuli Kaalam[15,17,27,28]	It is located in the first web space
5.	Asavu varmam[17,19,22,29]	It is located in the middle of the upper arm medially.
6.	Manibantha varmam[15,16,17,19,22,23,27,29]	It is located in the middle of the wrist joint.
7.	Thoosigam[17,22,29]	It is located in the nipple.

2.14. SAFETY EVALUATION

- Intolerance to the therapy and development of any serious adverse effects during the trial (If ADR is reported the patient will be directed to RPC)
- Patients turned unwilling to continue in the course of clinical trial
- Poor compliance.
- Any other acute illness which need rescue medication.

2.15. CRITERIA FOR OUTCOME ASSESSMENT

The result of the treatment is evaluated as to the degree of Pain according to Universal pain rating scale and to assess the severity of other symptoms using Self grading self-prepared rating scale for CS before and after treatment. The baseline features like Age, Sex, Socio economic status, occupation, diet, duration of illness were obtained by neck disability index questionnaire and physical examination. Radiographic changes of cervical vertebra were examined with x-ray images.

After the study period patients were followed for further 6 weeks through telephone to ascertain the recurrence of neck pain. The Statistical Analysis of the above said parameters was done using SPSS VER.17 of the 60 completed cases. Paired t- test is used to analyze the significance of change in Subjective parameters.

3. RESULTS & DISCUSSION

The result of various parameters studied is as follows:

3.1 Age wise distribution of CS patients who were subjected to Trial.

In the present study, out of 60 patients subjected the age wise distribution of the patients in age groups 20-30, 31-40, 41-50 and 51-60 years of age were 28.3%,26.7%,23.3% and 21.7%, respectively. Earlier reports suggested that CS is more prevalent in age group above 60 years whereas this study found no difference in distribution among age.

Table: 2.Following are the Demographical observations made in this clinical study.

BASELINE CHARACTERS	No. Of CASES (n= 60)	%
AGE IN YRS		
20-30	17	28.3
31-40	16	26.7
41-50	14	23.3
51-60	13	21.7
SEX		
Male	32	53.3
Female	28	46.7
OCCUPATION		
Coolie	4	6.7
Tailor	3	5.0
Carpenter	2	3.3
Drivers	7	11.7
Electrician	6	10.0
House wife	18	30.0
Sales men	5	8.3
Teacher	6	10.0
IT sector	9	15.0
SOCIO ECONOMIC STATUS		
Lower class	18	30.0
Middle class	20	33.3
Upper class	22	36.7
DIET HABIT		
Mixed diet	51	85.0
Vegetarian	9	15.0

3.2 Sex wise distribution of CS patients who were subjected to Trial.

Out of 60 patients, male and female patients were 53.3% and 46.7% respectively.

3.3 Occupation wise distribution of CS patients who were subjected to Trial

Out of 60 patients subjected in the present study, prevalence of the condition was highest in house wives (30.0%) followed by IT sector (15.0%). The prevalence in other categories in the descending order was found to be drivers (11.7%), salesmen (8.3%), coolies (6.7%), tailors(5.0%) and carpenter(3.3%). Occupation involving posture of prolonged neck flexion were attributing to the cause of CS was earlier reported. House wives and IT sector workers indulge in long hours of TV/monitor viewing which may attribute to the cause.

3.4 Socio economic class wise distribution of CS patients who were subjected to Trial

Out of 60 patients subjected in the present study, prevalence is higher among upper class patients (36.7%) than middle class (33.3%) and lower class (30.0%) respectively. There is no significant difference between the three classes studied though the patients in the upper class were observed to be slightly on the higher side.

3.5 Diet pattern wise distribution of CS patients who were subjected to Trial

Out of 60 patients subjected in the present study, mixed diet and vegetarian patients were 85.0% and 9.0% respectively.

3.6 Relationship of vatha, pittha and silaethuma predominant age of CS patients who were subjected to Trial

According to Siddha literature, Vatham period is upto 33.33 years of age, Pitha period is from 33.34 -66.67 years of age, Silaethuma period is from 66.68 – 100 years of age. The patients included in the study belonged only to vatha and pittha period of life. Incidence was more in Pittha period of life (65.0%) than in Vatha period of life (35.0%).

3.7 Distribution among different duration of CS in patients who were subjected to Trial

Out of 60 patients subjected in the present study, 11.7% belonged to less than one month of illness and others were 20.0% in 1-3 months, 30.0% in 4-6 months, 26.7% in 6-1 year and 11.7 % and in above 1 year. From the results, it is evident that cervical spondylosis condition is a slow developer without any clinical manifestation and that it is a chronic condition with no satisfactory specific treatment currently avail.

Table 3: Distribution among duration of illness

S.NO	DURATION OF ILLNESS	NO. OF CASES OUT OF 60	PERCENTAGE
1	Below 1 month	7	11.7
2	1 -3 month	12	20.0
3	4-6 month	18	30.0
4	6-1 year	16	26.7
5.	Above 1 year	7	11.7

3.8 Treatment outcome

The comparative study of *Villaiver kudineer*, *Varmam* therapy alone and combined therapy of both was done in three groups each comprising 20 patients. The patients response to *Villaiver Kudineer* alone (G1), *Varmam* therapy (G2) and in combined therapy of both *Varmam* and *Kudineer* (G3) was tried on 60 patients in three groups of 20 each the following inferences were made. Among group 1 patients (n=20), out of this, 58.21% responded, Among group 2 patients (n=20), out of this, 81.54% responded, Among group 3 patients (n=20), out of this, 82.71% responded.

The result of subjective parameters had revealed that Group 2 and Group 3 have shown significant improvement in reducing all symptoms of CS which is 81.54% and 82.71% respectively. About 80% of improvement was evident in neck pain, numbness, neck stiffness, movement restriction in G2, G3.

Table: 4. Clinical manifestations

S.NO	CLINICAL MANIFESTATIONS	No. OF PATIENTS				PERCENTAGE			
		Total 60	G1-20	G2-20	G3-20	Total %	Gp1%	Gp2%	Gp3%
1	Pain in the nape of neck	60	20	20	20	100	100	100	100
2	Radiculopathy	50	15	20	15	83.33	75	100	75
3	Sub-occipital pain	12	4	5	3	20	20	25	15
4	Numbness	45	15	12	18	75	75	60	90
5	Neck stiffness	40	11	10	19	66.6	55	50	95
6	Giddiness	4	1	1	2	6.6	5	5	10
7	Movement restriction	16	3	5	8	26.6	15	25	40

Table: 5. OVERALL RESULTS OF SUBJECTIVE PARAMETERS OF TREATMENTGROUPS-1, 2 & 3

SUBJECTIVE PARAMETERS	Response in G1				Response in G2				Response in G3			
	BT	AT	D	Res%	BT	AT	D	Res %	BT	AT	D	Res %
PAIN IN THE NAPE OF NECK	20	7	13	85.00	20	3	17	85.00	20	2	18	90.00
RADICULOPATHY	13	5	8	61.54	5	1	4	80.00	15	3	12	80.00
SUB OCCIPITAL PAIN	4	3	1	25.00	12	2	10	80.00	3	1	2	66.66
NUMBNESS	15	6	9	60.00	12	2	10	80.00	18	3	15	83.33
NECK STIFFNESS	11	4	7	63.33	10	2	8	80.00	19	3	16	84.21
MOVEMENT RESTRICTION	3	2	1	33.33	5	1	4	80.00	4	1	3	75.00
GIDDINESS	1	1	0	100.00	1	1	0	100.00	2	1	1	50.00
OVERALL PARAMETER	67	28	39	58.21	65	12	53	81.54	81	14	67	82.71

Table: 6 Comparision of signs & symptoms between pre and post evaluation of trail groups

SUBJECTIVE PARAMETERS	BT- Mean±SD			AT -Mean±SD			P value		
	G1	G2	G3	G1	G2	G3	G1	G2	G3
Pain in the nape of neck	2.150± 0.587	1.950± 0.825	2.200 ± 0.695	0.850 ±1.225	0.350 ±0.875	0.200 ± 0.615	0.001	0.001	0.001
Radiculopathy	1.10 ±1.020	0.40 ±0.75	1.45 ±1.09	0.55 ±1.050	0.10 ±0.44	0.40 ±0.99	0.004	0.005	0.001
Suboccipital pain	0.350 ±0.745	1.150 ±1.136	0.250 ±0.638	0.150 ±0.360	0.050 ±0.223	0.500 ±0.223	0.042	0.000	0.104
Numbness	1.40 ±1.046	1.15 ±1.136	1.70 ±0.923	0.60 ±0.994	0.25 ±0.786	0.35 ±0.875	0.002	0.001	0.001

Neck stiffness	1.05 ±1.099	0.900 ±0.967	1.650 ±0.812	0.50 ±1.051	0.200 ±0.615	0.350 ±0.878	0.008	0.003	0.001
Movement restriction	1.20 ±0.523	0.40 ±0.754	0.60 ±0.821	0.15 ±1.489	0.10 ±0.44	0.15 ±0.489	0.330	0.055	0.016
Giddiness	0.100 ±0.447	0.050 ±0.223	0.150 ±0.489	0.100 ±0.447	0.050 ±0.223	0.100 ±0.447	0.008	0.001	0.330

In all earlier studies cervical spondylosis is described as equivalent to ceganavatham[30] in Siddha pathology literatures. When we compare the clinical manifestation of CV with CS, the clinical manifestation of Pidari vatham seems to be nearer to cervical spondylosis. Hence it may be suggested that pidari vatham may be substituted for Cegana vatham in future. This is the first authenticated treatment protocol trial employing manipulation of varmam and internal medicine as observed from literature scanned. In the present study 60 patients with inclusion criteria and exclusion criteria mentioned as above were grouped into three groups between the age group of 20-60 years. The study period was between Jan 2014 and Jan 2015. The groups were designated as G1, G2 and G3; G1 was subjected to *Villaiver kudineer* alone, G2 was subjected to Varmam manipulation alone and G3 with both. Observation period was fixed at six weeks.

Trial drug VVK consisting of 40 constituents was described in at least three varmam literatures and claimed to have efficacy in correcting Enbu & narambu kayam. This is the basis of selection of hitherto unexplored and tried composition. This formulation was supposed to be given as Kudineer (decoction). It has to be prepared and used generally within 3 hours. To avoid wastage and unpredictable nature of desired patients visiting the OPD the composition was made into pockets of seventy grams and given to the participants of the appropriate groups.

The analytical testing as per AYUSH protocol for evaluating *kudineer churanam* exemplified that the polyherbal formulation *Villaiver kudineer* has no heavy metals as per ICP-MS, no microbial contamination, absence of pathogenic bacteria and fungi. Acute and 28 days repeated dose oral toxicity study of *Villaiver kudineer* in swiss albino rats revealed that the drug was safe. Histopathological studies have shown that the drug has no toxic effects in the vital organs. Analgesic activity of villaiver kudineer in animal model in acetic acid induced writhing test indicated that villaiver kudineer had shown dose dependent activity against standard diclofenac sodium. *In vivo* anti inflammatory activity of the test drug in carageenan induced paw edema method revealed that the drug has anti inflammatory activity with reference drug indomethacin[31].

Varmam points for manipulation were selected based on varmam classical literature. The varmam points stimulated as per treatment protocol were *Pidari kalam, Mudichu varmam, Kakkatai kalam, Manibantha varmam, Asavu varmam, Kavuli kalam* and *Thoosumugam varmam.* This Varmam methodology was stimulated for the group 2 and 3. The review on varmam literatures gives evidence that varmam points are related to the physiological functions of the body. For instance, the *pidari kalam* stimulates the *idakalai nadi*, *mudichu varmam* strengthens the head and neck; *kakkatai kalam* supplies energy to whole body below neck and helps in the rotatory movement of neck; *asavu varmam* helps in the movement of upper limb and it also strengthen shoulder joint; *kavuli kalam* gives strength to shoulder joint[21], *thoosumuga* varmam serves as an anchorage to the neck facilitating the movement of neck [21]

As neck, shoulder, upper limb are involved in manifesting the symptoms of CS stimulation of these varmam points might helped to get rid of its symptoms. The special emphasis on movement of neck with respect to *kakkatai kalam*, *thoosumuga varmam* might help in improving the movements of CS patients. *Asavu varmam* would have played a role in reducing the radiating pain in upper limb. Combined therapy was advocated for the group 3 patients.

However stimulation of *Varmam* points helped greatly to reduce sub occipital pain, the sample size examined was very low. The predominant symptom of CS neck pain was found to be pacified by all three treatment methodology, although combined treatment had given 90% of relief. The study paves way to envisage that the external therapy Varmam shall also be employed as a single treatment protocol for the management of CS. This is evident from the present study showing no much difference between the G2 and G3.

Although, there was no difference between the objective parameters before and after treatment revealed from laboratory parameters and radiological findings. Since the P value is highly significant (P<0.001).so there is significant reduction of pain scale score and other gradation scale score among the patients of three groups. The G3 (82.71%) shows highly effective when compared to G2 (81.54) and G1 (58.21) for treatment of CV. Thus, comparatively group 3 which was given both *Villaiver Kudineer* and *Varmam* therapy had shown significant improvement with symptomatic management in CS.

CONCLUSION

Cervical spondylosis which is becoming very common in present day life can be shown a new path with the Siddha drug *Villaiver kudineer* which have proven safety and efficacy studies with pharmacological activity and have shown significant improvement in clinical trial. The results of clinical study and statistical analysis of

symptoms of CS revealed that there was no significant difference between the G2 and G3, however G3 showed relatively good improvement, which in turn indicates that the drug and Varmam intervention is the better choice to get rid of symptoms arising from **CS**. Varmam therapy markedly reduced the symptoms and improved the quality of life. Further combination of both *Villaiver kudineer* and *varmam therapy* has shown noteworthy improvement in assuaging the symptoms of **CS.**

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