

A Study on the Efficacy of *Guggulu* along with *Haridra* and *Rasnadashmooladi Kashaya* and *Siravyadha* in *Krostukasirsa* w.s.r. To Non-Specific Knee Effusion

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ABSTRACT

Changing life style in present era is the main cause of the prevalence of many diseases which are leading to certain pre age degenerations. Knee effusion is a disease secondary to degenerative changes/excessive body weight/excessive wear tear /trivial or evident trauma to the knee joint or condition associated Non-specific arthropathies. This condition can be defined as the abnormal accumulation of the fluid in the knee capsule or the adjoining supra-patellar bursa secondary to the irritation/inflammation of sub-acute strength in the joint synovium. As per Ayurveda this condition is usually found to be associated with the diseases like *Amavata*, *Vatrakta*, *Sandhigata Vata*, *Krostukasirsa* and other related arthropathies explained in *Ayurveda*. *Krostukasirsa* as described in *Ayurveda*, can be correlated with Non specific knee effusion. There is no promising management available till date for the management of this condition. Here, an attempt has been formulated to establish a remedy to the problem by proving the efficacy of *Guggulu* along with *Haridra* and *Rasnadashmooladi Kashaya* and also to establish the efficacy of *Siravyadha* along with *Guggulu*, *Haridra* and *Rasnadashmooladi Kashaya* in *Krostukasirsa* w.s.r. to Non-specific knee effusion. The study is conducted over 50 patients from OPD and IPD of National Institute of Ayurveda, Jaipur in two different groups to assure the more relevant approach regarding Non- specific knee effusion through Ayurveda conservatives (oral along with *Siravyadha*).

Key words: *Krostukasirsa*, Non-specific knee effusion, *Siravyadha*.

INTRODUCTION

Non-Specific knee effusion is a disease secondary to degenerative changes /excessive body weight / excessive wear and tear / trivial or evident trauma to the knee joint or other conditions associated with Non-specific knee arthropathies. This condition can be defined as the abnormal accumulation of the fluid in the knee capsule or the adjoining supra-patellar bursa secondary to the irritation/inflammation of sub-acute strength in the joint synovium.

This condition is usually found to be associated with the diseases like *Amavatta*, *Vatrakta*, *Sandhigata Vata*, *Krostukasirsa* and other related arthropathies explained in *Ayurveda*. *Krostukasirsa* as described in *Ayurveda*, can be correlated with Non specific knee effusion.

Krostukasirsa, as described in *Ayurveda*, can be correlated with Non-specific knee effusion. *Acharya Sushruta*,^[1] *Acharya Vagbhatta*, *Bhavprakash*, *Madhavkar*, *Chakrapani Dutta* has described that vitiation of *Vata* and

RaktaDosha is considered to be the main pathogenesis in concern to this condition.

Acharya Sushruta has described Aaghat (trauma), Amvatta, Sandhivata (non specific arthropathies), Updansha (infective arthropathies) as its aetiological factors and Shoth (inflammation), Maharuj, Pida (pain) as the main clinical features of this condition.

While describing treatment of Krostukasirsa stress has been given on the pacification of vitiated Vata and RaktaDosha through VataSanshmana (anti-inflammatory measures) and Siravyadha.

Non specific knee effusion (Krostukasirsa) is progressive degenerative disorder more commonly found in females after the age of 35 years. The condition is more prevalent in obese and person involved in exertional activities.

NEED OF STUDY:

Currently available conservative treatment mode for Non-specific knee effusion are mainly restricted to non-steroidal anti-inflammatory drugs which exhibit numerous side effects and are only temporarily effective.

A clinical study to evaluate anti-inflammatory effect of *Commiphora wightii* and *Boswellia serrata* individually, along with *Curcuma longa* with Diclofenac potassium [NSAID'S] taken as standard measure had been undertaken previously with noteworthy results in the department of *Shalya Tantra*, NIA Jaipur. Two more similar studies have been conducted with encouraging results. One study with *Guggulu* and *Sallaki* along with *Haridra* and *Guduchi Kashaya* in *Krostukasirsa* w.s.r. to Non-specific knee effusion and other study with *Birhat Simhanada Guggulu*, *Godanti*, *Rasamanikya* with *Maharasnadi Kashaya* in *Janu Sandhi Shleshmadhara Kala Shoth*. Taking the leads from previous studies and following the references of *Chakradutta and Acharya Sushruta* for *Rasnardashmooladi Kashaya*^[2] and *Siravyadha* respectively the present study has been conducted to access the efficacy of *Guggulu* along with *Haridra* and

Rasnardashmooladi Kashaya and *Siravyadha* in *Krostukasirsa* w.s.r. to Non-specific knee effusion.

AIMS AND OBJECTIVES:

Primary Aims

- Assessment of therapeutic efficacy of *Guggulu* (*Commiphora wightii*) accompanied by *Haridra* (*Curcuma longa*) along with *Rasnardashmooladi Kashaya* in *Krostukasirsa* w.s.r. to Non-specific knee effusion.
- Assessment of therapeutic efficacy of *Guggulu* accompanied by *Haridra* along with *Rasnardashmooladi Kashaya* and *Siravyadha* in *Krostukasirsa* w.s.r. to Non-specific knee effusion.
- Inter group comparisons in between the trial groups.
- Analysis of information regarding the toxicity/adverse effect of *Guggulu*, *Haridra* along with *Rasnardashmooladi Kashaya*.

Secondary Aims

- To study the incidence of knee effusion among the patients having non-specific arthritis of knees.
- To make available cheap, economic and less side effect formulation/regimen for the treatment of Non-specific knee effusion.

MATERIAL AND METHODS

Total 50 patients were registered for study. So, all observations were made on 25 patients each in the two groups.

Trial duration -2 months

Clinical assessment as per research protocol for statistical analysis was done on 0 day, at the end of 4th week & then at the end of 8th week.

Follow up - 4 months

Follow up will be taken every month for further 4 months.

Selection Criteria

Inclusion Criteria:

- Patients in the age group 15-65 yrs. of either gender having Non-specific knee effusion.
- Patients who were willing for trial and ready to give written informed consent.

- Patients were selected randomly irrespective of economical, educational and marital status.

Exclusion Criteria:

- Patients not ready to give an informed consent.
- Patients suffering from specific knee effusions due to various types of arthritis, trauma, hemarthrosis etc.

Assessment Criteria

Assessment of affected knee joint will be done on following criteria.

- Pain As on Visual Analogue Scale
- Tenderness Ritchie Index
- Walking Distance 6MWT
- Swelling Circumferential Variation
- ROM using Goniometer

Investigations

The following investigations will be carried out before starting the research work.

A. Radiological investigation

- X-Ray knee joint (Antero-Posterior & Lateral view)

B. Haematological investigation

- Haemoglobin gram %
- Erythrocyte Sedimentation Rate
- Total Leucocyte Count
- Differential Leucocyte Count
- Blood Sugar
- Blood Urea
- S.Creatinine
- Lipid Profile [if required]
- CT & BT [if required]

C. Serological investigations

- R.A. Factor
- Anti Streptolysin O [ASLO] Titer
- C-Reactive Protein
- Serum Uric acid
- HIV [if required]
- HBsAg [if required]

D. Urine examination (routine and microscopic)

E. Cytology of diagnostic aspirate (If required)

F. Mantoux / ELISA for Tuberculosis (If required)

G. Synovial Biopsy (if required)

Study Type: Interventional

Study Design

Randomized prospective unicentric clinical study

Sample size: total 50 patients

Computer generated random table for 50 patients.

Total 50 patients were registered for study. So all observations were made on 25 patients each in the two groups.

Group-A

- Drugs: Dried crude extract of *Guggulu* (*Commiphora wightii*) and *Haridra* (*Curcuma longa*)
- Dosage: Capsule of 500mg each.
- *Anupana-Rasnashmooladi Kashaya* 50 ml.
- Route- orally
- Regimen-Twice daily for 8 weeks.

Group-B

- Drugs: Dried crude extract of *Guggulu* (*Commiphora wightii*) and *Haridra* (*Curcuma longa*)
- Dosage: Capsule of 500mg each
- *Anupana-Rasnashmooladi Kashaya* 50 ml
- Route-orally
- Regimen-Twice daily for 8 weeks
- Procedure- *Siravyadha* 4 sittings (initiation of the trial, 15th day, 30th day, 45th day).
- Site-*Siravyadha* [venepuncture] done in the affected leg four finger above *Gulfa* (ankle) about 20 ml venous extracted in every sitting. [3]

All drugs were procured and supplied in the form of capsules by the GMP certified NIA pharmacy.

Crepe bandage application was advised to the patients of both groups at the time of weight bearing.

Clinical assessment as per research protocol for statistical analysis was done on

- Starting of trial
- At the end of 4th week
- At the end of 8th week.

STATISTICAL ANALYSIS

OUTCOME OF STATISTICAL ASSESSMENT OF SIGNS/SYMP TOMS IN GROUP A

(By Wilcoxon matched paired test) [4]

Table No. 1-Showing outcome of statistical assessment of Signs / Symptoms in Group A:-

S.no.	Assessment Parameters	Mean B.T.	Mean A.T.	Difference	% Relief	S.D.	S.E.	P Value	Result
1.	Pain	4.600	2.200	2.400	52.17	0.957	0.191	<0.0001	ES
2.	Tenderness	1.600	0.640	0.960	60	0.454	0.090	<0.0001	ES
3.	Effusion	1.360	0.680	0.680	50	0.476	0.095	<0.0001	ES
4.	Walking distance	2.880	1.160	1.720	59.72	0.737	0.147	<0.0001	ES
5.	R.O.M.	2.440	1.320	1.120	45.90	0.331	0.066	<0.0001	ES

OUTCOME OF STATISTICAL ASSESSMENT OF SIGNS/SYMP TOMS IN GROUP B

(By Wilcoxon matched paired test)

Table No.2-Showing outcome of statistical assessment of Signs/Symptoms in Group B:-

S.no.	Assessment Parameters	Mean B.T.	Mean A.T.	Difference	% Relief	S.D.	S.E.	P Value	Result
1.	Pain	4.080	1.840	2.240	54.90	0.663	0.132	<0.0001	ES
2.	Tenderness	1.680	0.480	1.200	71.42	0.500	0.100	<0.0001	ES
3.	Effusion	1.480	0.520	0.960	64.86	0.351	0.070	<0.0001	ES
4.	Walking distance	3.040	1.160	1.880	61.84	0.600	0.120	<0.0001	ES
5.	R.O.M.	3.040	1.560	1.480	48.68	0.585	0.117	<0.0001	ES

INTER GROUP COMPARISON OF SIGNS/SYMP TOMS IN GROUP A AND GROUP B

(By Mann-Whitney test) [5]

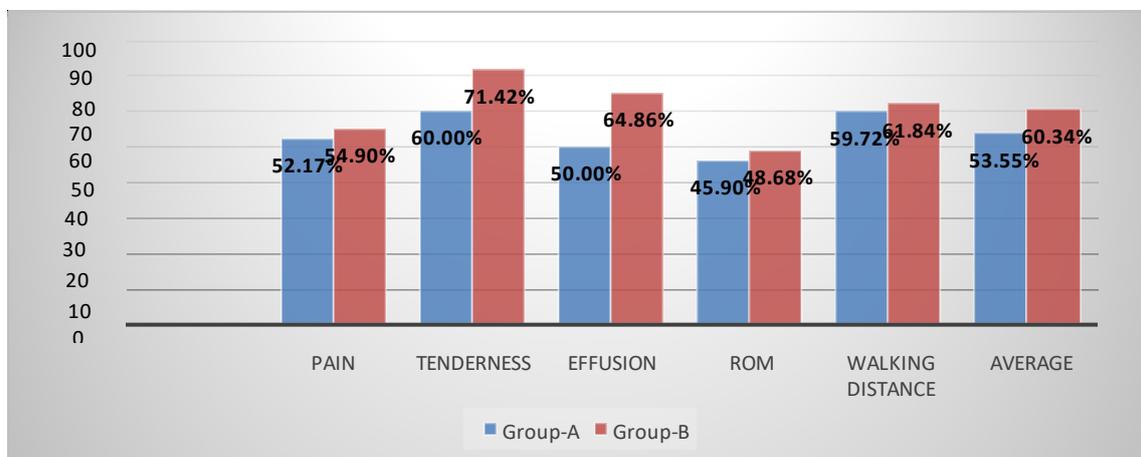
Table No. 3- Showing inter group comparison of Signs/Symptoms in Group A and Group B:-

Variable	Groups	Mean	Standard deviation S.D. ±	Standard Error S.E. ±	P	Result
Pain	A	2.40	0.957	0.191	0.2688	NS
	B	2.240	0.663	0.132		
Tenderness	A	0.960	0.454	0.090	0.0984	NS
	B	1.200	0.500	0.100		
Effusion	A	0.680	0.476	0.095	0.0252	NS
	B	0.960	0.351	0.070		
Walking distance	A	1.720	0.737	0.147	0.3343	NS
	B	1.880	0.600	0.120		
Range of movements	A	1.080	0.276	0.055	0.0040	VS
	B	1.480	0.585	0.117		

ES-Extremely significant, VS-Very significant, NS- Non significant

RESULTS

The average relief in sign and symptoms in group A was 53.55 % and in group B was 60.34 % which indicates that difference in average relief in sign and symptoms in 2 groups was insignificant.



AVERAGE RELIEF OF SIGN AND SYMPTOMS

Sign & symptoms	Group-A	Group-B
Pain	52.17%	54.90%
Tenderness	60%	71.42 %
Effusion	50%	64.86 %
ROM	45.90 %	48.68 %
Walking distance	59.72 %	61.84 %
Average	53.55 %	60.34 %

DISCUSSION

- Non-specific knee effusion can be cited as a life style disorder.
- The main etiological factor for Non-specific knee effusion among the study subjects was irritation/inflammation of synovial lining of the affected knee.
- This is caused due to excessive body weight as per BMI, long standing and walking.
- As per the presenting sign and symptoms which are pain, swelling, stiffness and restricted movements, Non-specific knee effusion can be correlated to *Krostukasirsa* mentioned in by *Acharya Sushruta*.

PROBABLE MODE OF ACTION DRUGS

Anti-inflammatory and anti-arthritis activity of *Guggulu* can be attributed to its *Tikta, Katu Rasa, Laghu, Ruksha, Tikshna Guna, Ushna Veerya* and *Katu Vipaka* hence *Vata & Kapha Shamaka* character. [6]

Anti-inflammatory nature of *Haridra* is due to its *Tikta, Katu Rasa, Ruksha, Laghu Guna, UshnaVeerya* and *KatuVipaka* hence *Vata & Kapha Shamaka* character. [7]

Anti-inflammatory, anti-rheumatic, analgesic and rejuvenating activity of *Rasnashmooladi Kashaya* can be attributed to its *Tikta, KasayaRasa, Laghu Guna, UshnaVeerya* and *Madhura Vipaka* hence *Tri-Dosha Shamaka* character.

SIRAVYADHA

Raktamokshana (Bloodletting) is the *Shodhana* (purification) therapy and is recommended to remove the vitiated *Dosha* from the nearest route of *Roga Adhithana*, for correction of vitiated *Dosha* to reinstate the *Tri-Dosha* equilibrium. *Siravyadha* is indicated predominantly in *Pitta, Rakta* and

Kaphaja Vyadhi or when *Pitta* or *Kaphais* in *Anubandha* to *VataDosha*. *Siravyadha* removes the *Avarana* of *Kapha* or *Pitta Dosha* giving way for *Anulomana* indirectly cures the *Vatika* symptoms along with *pitta* or *Kapha Dosha* and patient gets immediate relief in sign and symptoms. [8]

The therapeutic effects of bloodletting can be explained as per the contemporary science through various postulates like removal of circulating mediators of inflammation, removal of end products of metabolism, improved perfusion, improved metabolism, improved tissue repair, improved sympathetic nerve function, improved immune mechanism leading to the improvement or cure of the conditions [9]

CONCLUSION

- As per the presenting signs and symptoms Non-specific knee effusion considered in study can be correlated with *Krostukasirsa*.
- Maximum numbers of patients were of age group in between 36-45 years of age.
- Patients with *Vata-Pitta* and *Vata-Kapha Prakriti* were observed more likely to suffer from Non-specific knee effusion.
- The condition was found to be more prevalent in persons above the age of thirty five, obese individuals or the individuals engaged in extraneous activities.
- Swelling, pain and tenderness are the sure evidences for knee effusion.
- Pain and swelling were the two important and troublesome symptoms of knee effusion which sought an immediate clinical attention.
- Group B in which the intervention was done with *Guggulu, Haridra* and *Rasnashmooladi Kashaya* along with *Siravyadha* was found to be slightly more effective & presented with % relief of 60.34% in comparison to group A in which the intervention was done with *Guggulu, Haridra* and *Rasnashmooladi Kashaya* % relief of 53.55%.

- After statistical analysis it was observed that difference in % relief in between group A and group B appears to be insignificant with p value 0.0252.
- All three drugs-Guggulu, Haridra and Rasnashmooladi Kashaya along with Siravyadha under trial exhibited anti-inflammatory and analgesic property.
- The synergistic effect of interventions in both groups is found to be effective in relieving the signs and symptoms of Krostukasirsa (Non-specific knee effusion) due to their anti-inflammatory, analgesic, anti-arthritis and rejuvenating properties.
- No untoward effect of any intervention has been reported by the patients or observed during the course of study and follow up.

Therefore, it can be concluded that management of Non-specific knee effusion through Ayurveda conservatives are found to be safe and effective.

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