

A RANDOMIZED COMPARATIVE CLINICAL TRIAL TO EVALUATE THE EFFICACY OF RASNADIKWATHGHANVATI WITH RASNADIGUGGULE IN KATIGATAVATA

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ABSTRACT

Katigatavata is a disease which can be explained under the concept of gatavata giving idea for different vatavyadhis in Ayurveda. Katishool is one of the most common complaint seen in current scenario. According to Ayurveda this complaint is described for old age patients where the phase of vata vitiation starts but changing life styles & eating habits, exertion, jerking activities during travelling, sports, abnormal sitting postures etc, are causing katishool in any age group mostly middle age. Symptoms like katishool, katigrah, are present in katigatavata. In present study 62 patients were selected. These were divided into two equal groups and treated with rasnadi kwath ghanvati and rasnadi guggul respectively. Observations were recorded for different subjective and objective parameters of katigatvat. Obtained data was analysed by using statistical test. Efficacy of both groups is compared.

KEYWORDS: Katigatvat, Rasnadi kwath ghanvati, Rasnadi guggul.

INTRODUCTION

As per the prevalence rate, Katigat vata is a very common disease observed in now a days in all ages groups in the society. Katigatavata can be correlated with low back pain or Lumbago. Lumbago/Low back pain is experienced approximately in 60-80% of adults at some point in their lifetime. The present age speed and competition had increased stress and strains

resulting into increase in prevalence of life style disorders. Andersson estimated that annual worldwide low back pain incidence in adults is 15% and the point of prevalence to be 30%. Lumbar pain episodes and injuries exceed to miss number of working days compared to common cold. This disease not only causes pain but also causes difficulty in daily routine activities making life unhappy. It is referred to as the 2nd frequent reason for visiting doctor, 3rd frequent reason for surgery and 5th frequent reason for hospitalization. Modern medicine is lacking in effective treatment due to use of only pain killers or calcium supplementations though it has many side effects.

So considering need of the society and all the above points, the study had been undertaken.

OBJECTIVES

1. To evaluate the efficacy of Rasnadi kwath ghanvati in katigatvat
2. To evaluate the efficacy of Rasnadi guggul in katigatvat
3. To compare the efficacy of Rasnadikwath ghanvati with Rasnadi guggul in Katigatavata.
4. To observe adverse drug reaction, if any.

METHODOLOGY

Clinical Study

Type of Clinical Study: Randomised Comparative Clinical Trial.

Location: Present clinical study included patients were from OPD, IPD of Kayachikitsa Department, from attached Ayurveda Hospital of PDEA's College of ayurveda and research centre, Nigadi, Pune

Study population: Patients of age between 30-60 having classical sign and symptoms of katigataVata.

▪ Inclusion criteria

1. Patients having 3 or more following symptoms since minimum one month
 - Katishool
 - Katigraha(stambh)
 - Sparsha-asahatwa
 - Sphutana
 - Akunchana Prasara Vedana
2. Patients of age between 30 - 60 years irrespective of gender
3. X-ray of lumbar spine done to evaluate changes, if any

▪ Exclusion criteria

1. Patients suffering from any known case of severe systemic disorders.
2. Known case of Rheumatoid Arthritis, Psoriatic arthritis, Gouty arthritis, Systemic lupus erythematosus.
3. Pot's spine (TB), Paralysis, Neurological disorders.
4. Pregnant and Lactating woman.
5. Patients having congenital structural deformities.
6. Fracture of lumbar spine and any other traumatic causes of spine which needs surgical care excluded.

▪ Criteria for Withdrawal

1. Occurrence of any serious adverse events
2. Patient himself/herself want to withdraw from clinical trial
3. Patient not giving proper follow up

❖ Therapy Plan

Group A= 31= Rasnadikwathghanvati (Trial Drug)

Group B= 31= Rasnadi Guggul (Control Drug)

Drug	Rasnadi kwath ghanvati (Group A)	Rasnadiguggul (Group B)
Route of Administration	Orally	Orally
Dose	500 mg -2 tab	500 mg- 2tab
Sevankal	vyan-udan kaal	vyan-udan kaal
Anupan	Ghrit(3 ml)+Erantail(5 ml)	KoshnaJala
Duration	21 days	21 days
Follow up	7 th , 14 th , 21 st day	7 th , 14 th , 21 st day

Sampling technique: Patients of KatigataVata were selected by Simple random method by lottery technique in two groups.

Criteria for Assessment/Method of measurement

The effect of therapy assessed on the basis of changes in signs and symptoms in both groups. The detailed assessment of cardinal signs & symptoms are discussed below. To assess the effect of therapy objectively, all the signs and symptoms were given scoring depending upon their severity.

The following signs and symptoms will be assessed.

- Complete Remission: 100%

- Maximum Improvement: > 75% to < 100%
- Moderate improvement: > 50% to < 75%
- Mild improvement: > 25% to < 50%
- No improvement: 0% to < 25%

1. Assessment according to Ayurveda

Katishool

No backache	0
Occasionally	1
Relieves by medicine	2
Dependent on medicine	3

Katigrah/katistambh

No stiffness	0
Stiffness for few minutes relieved by mild movements	1
Stiffness lasting for 1-2 hours but routine works are not disturbed	2
Stiffness lasting for more than 2 hours mildly affecting the daily routine	3
Episodes of stiffness lasting for 2-6 hours, daily routines are hampered	4

Aakunchanprasaranvedana (pain during flexion and extension)

No pain	0
Pain without winching of face	1
Pain with winching of face	2
Prevent complete flexion	3
Does not allow passive movements	4

SparshaAsahtwa (Tenderness)

No tenderness	0
Patient feels tenderness	1
Winching of face on touch	2
Does not allow to touch the joint	3

Sandhisphutana (Crepitus)

No crepitus	0
Palpable crepitus	1
Audible crepitus	2

Overall assessment according to ayurvedic criteria

Score	Severity of disease
1-5	Mild
6-10	Moderate
11-16	Severe

Assessment criteria (modern view)**SUBJECTIVE**

1. Oswestry low back pain disability Questionnaire

OBJECTIVE

1. VAS score
2. coin test
3. Walk test

SUBJECTIVE CRITERIA**1. OSWESTRY LOW BACK PAIN DISABILITY QUESTIONNAIRE**

This test is considered as the “gold standard” of low back function outcome tools.

Section 1 – Pain intensity

0	I have no pain at the moment
1	The pain is very mild at the moment
2	The pain is moderate at the moment
3	The pain is fairly severe at the moment
4	The pain is very severe at the moment
5	The pain is the worst imaginable at the moment

Section 2 – Personal care (washing; dressing;)

0	I can look after myself normally without causing extra pain
1	I can look after myself normally, but it causes extra pain
2	It is painful to look after myself and I am slow and careful
3	I need some help, but manage most of my personal care
4	I need help every day in most aspects of selfcare
5	I do not get dressed; I wash with difficulty and stay in bed

Section 3 – Lifting

0	I can lift heavy weights without extra pain
1	I can lift heavy weights, but it gives extra pain
2	Pain prevents me from lifting heavy weights off the floor, but I can manage if they are conveniently positioned, for example- on a table
3	Pain prevents me from lifting heavy weights, but I can manage light to medium weights if they are conveniently positioned
4	I can lift very light weights
5	I cannot lift or carry anything at all

Section 4- Walking

0	Pain does not prevent me walking any distance
1	Pain prevents me from walking more than 2 kilometers
2	Pain prevents me from walking more than 1 kilometer
3	Pain prevents me from walking more than 500 meters
4	I can only walk using stick or crutches
5	I am in bed most of the time

Section 5 – Sleeping

0	I have no trouble sleeping.
1	My sleep is occasionally disturbed.
2	My sleep is mildly disturbed due to pain (less than 6 hours of sleep)
3	My sleep is moderately disturbed due to pain (less than 4 hours of sleep)
4	My sleep is greatly disturbed due to pain (less than 2 hours of sleep)
5	My sleep is completely disturbed

Section 6 – Sitting

0	I can sit in any chair as long as i like
1	I can only sit in arm chair as long as i like
2	Pain prevents me sitting more than one hour
3	Pain prevents me from sitting more than 30 minutes
4	Pain prevents me from sitting more than 10 minutes
5	Pain prevents me from sitting

Section 7 - Standing

0	I can stand as long as I want without extra pain
1	I can stand as long as I want but it gives me extra pain
2	Pain prevents me from standing for more than 1 hour
3	Pain prevents me from standing for more than 30 minutes
4	Pain prevents me from standing for more than 10 minutes
5	Pain prevents me from standing at all

Section 8 – Travelling

0	I can travel anywhere without pain
1	I can travel anywhere but it gives me extra pain
2	Pain is bad but i manage journeys over two hours
3	Pain restricts me to journeys of less than one hours
4	Pain restricts my journey of less than 30 minutes
5	Pain prevents me from travelling except to receive treatment

1. Each of the 8 sections is scored separately (0 to 5 points respectively) and then added up (max. total = 40).
2. If all 8 sections are completed, simply double the patients score.
3. If a section is omitted, divide the patient's total score by the number of sections completed times 5.

Formula: % DISABILITY = PATIENT'S SCORE / NO.OF SECTIONS COMPLETED X 100

If the first statement is marked the section score = 0; if the last statement is marked, it = 5. The score are than calculated in percentage.

0% to 20%: minimal disability	The patient can cope with most living activities. Usually no treatment is indicated apart from advice on lifting sitting and exercise
21%-40%: moderate disability	The patient experiences more pain and difficulty with sitting, lifting and standing. Traveling is more difficult and they may be disabled from work. Personal care and sleeping are not grossly affected and the patient can usually be managed by conservative means
41%-60%: severe disability	Pain remains the main problem in this group but activities of daily living are affected. These patients require a detailed investigation
61%-80%: crippled	Back pain impinges on all aspects of the patient's life. Positive intervention is required.
81%-100%	These patients are either bed-bound or exaggerating their symptoms.

OBJECTIVE CRITERIA

1) VAS SCALE

For pain assessment most frequently used tool is VAS (visual analogue score) scale

Using a ruler distance is measured on a 10 cm line.

0	10	20	30	40	50	60	70	80	90	100
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The respondent is asked to indicate the numeric value of segmented scale that best

Describes the pain intensity on ruler scale. Higher the score, greater the pain.

2) WALKING TIME

Walking time of patients for the distance of 10 meters will be recorded on 0th, 7th, 14th, 21st.

10m walking	0 th day	7 th day	14 th day	21 st day
Time				

3) COIN TEST

Angle of bending will be measured with the help of Goniometer.

Observation	0 th day	7 th day	14 th day	21 st day
Angle of bending				

Patients were assessed before treatment and after treatment on the basis of scores, other criteria and results will be drawn.

Good result: No complaints

Moderate results: 2 steps down

Mild results: 1 step down

No result: No change in complaints

❖ OBSERVATIONS & STATISTICAL STUDY

General observations done for following aspects in both groups = Age, Gender, Prakruti,

Occupation, BMI, Agni, Koshtha.

STATISTICAL ANALYSIS

In both groups, control and trial samples used for data analysis is 31. On each sample 09 parameters are measured. Out of them 6 Subjective Parameters are ordinal (qualitative) and 3 Objective Parameters are quantitative in nature.

Qualitative and Quantitative parameters are measured in 3 follow ups.

According to type of parameter the appropriate statistical tests are as follows:

Type of variable	What is going to check	Appropriate test
Ordinal	Before and after treatment results	Wilcoxon test
Quantitative	Before and after treatment results	Paired t test

These tests are applied in SPSS software the results are as follows:

According to % Relief in Symptoms

Table: % Relief in Symptoms of both groups.

Sr. No.	Symptoms	% Relief	
		Group A	Group B
1	Katishool	85.71	53.97
2	Katigraha	87.5	55.77
3	AKPR Vedana	89.8	68.09
4	Sprashasahatva	85.71	66.67
5	Sandhi sputana	100	100
6	Avg. % Relief	89.74	68.89

According to Avg. Change in objective parameter

Table: Avg. Change in Change in objective parameter of Group A & Group B.

Sr. No.	Parameters	Avg. Change	
		Group A	Group B
1	OLBD	22.6	11.2
2	VAS	4.48	2.61
3	Coin test	6.77	3.39
4	Walk test	1.23	0.65

According to statistical analysis

A. Subjective Parameters

Wilcoxon Signed Ranks Test

Subjective criteria	GROUP A (N=31)					GROUP B (N=31)			
		mean	median	W	P	mean	median	W	P
Katishool	BT	2.032	2	496	<0.0001	2.032	2	465	<0.0001

	AT	0.290	0			0.935	1		
Katigrah	BT	1.806	2	465	<0.0001	1.667	2	378	<0.0001
	AT	0.225	0				0.741		
Akunchan prasaran vedana	BT	1.581	2	496	<0.0001	1.516	1	435	<0.0001
	AT	0.161	0				0.483		
Sparshasahatva	BT	0.225	0	21	0.0313	0.193	0	10	0.1250
	AT	0.032	0				0.064		
Sandhi sputan	ONLY 3 PATIENTS WERE FOUND					ONLY 2 PATIENTS WERE FOUND			

Mann whitney's test

Symptom	Group	mean	Mean Rank	U	P
Katishool	A	1.742	40.70	195	<0.0001
	B	1.097	22.29		
Katigrah	A	1.581	40.30	207.5	<0.0001
	B	0.935	22.69		
Akunchan prasaran vedana	A	1.419	37.08	307.5	0.0125
	B	1.032	25.91		
Sparshasahatva	A	0.193	32.5	449.5	0.6539
	B	0.129	30.5		
Sandhi sputana	3 patients of Group A & 2 Patients of Group B were found				

Table: Overall Effect of Therapyas per Statistical analysis.

Sr. No.	Subjective Parameters	Within Groups (Wilcoxon test)		Comparison (Mann-Whitney's test)
		Group A	Group B	
1	Katishool	Significant	Significant	Significant (A > B)
2	Katigraha	Significant	Significant	Significant (A > B)
3	AKPR vedana	Significant	Significant	Significant (A > B)
4	Sparshaashtva	Undefined	Undefined	Undefined
5	Sandhi sputana	NA	NA	NA

(NA – Not applicable)

B. Objective Parameters

Table: Overall Effect of Therapyas per Statistical analysis.

Sr. No.	Objective Parameter	Within Groups (Paired t test)		Comparison (Unpaired t test)
		Group A	Group B	
1	OLBD	Significant	Significant	Significant (A > B)
2	VAS	Significant	Significant	Significant (A > B)
3	Coin test	Significant	Significant	Significant (A > B)
4	Walk test	Significant	Significant	Insignificant (A ≈ B)

(≈ - means statistically equal, not exact equal)

Overall Effect of Therapy**According % Relief****Table: Overall Effect of Therapy according % Relief.**

Sr. No.	Criteria	Improvement Grade	No. of patients		No. of symptoms*	
			Gr. A	Gr. B	Gr. A	Gr. B
1	100%	Complete	18	01	00	00
2	75% to 99%	Maximum	06	08	04	00
3	50% to 74%	Moderate	07	18	00	04
4	25% to 49%	Mild	00	03	00	00
5	00% to 24%	No	00	01	00	00

* (Sandhi Sputana symptom excluded)

❖ DISCUSSION

- Katigata vata/Low back pain is explained under the concept of Sandhigata vata. The vitiated Vata Dosha lodges in joints causing Sandhigata Vata. When it is lodged at kati or pelvic area it is called as Katigata vata. Now a days due to different physical stress the pathology is happening in earlier ages too.
- Dravyas having properties like Vataghna, Vatanulomana, Vedanasthapana, Shoolaprashamana, Shothahara are useful in the treatment of Katigata Vata. - As every shoola is due to imbalance of vata, it is necessary to correct the gati of vata which is anuloma in nature and aama is the main cause for any disease so pachan is required which is best done by tikta dravyas. Strengthening the part improves the capacity and longevity of it providing swasthya to the patient.
- In Rasnadi Kwath ghanvati,
 - Rasna and guduchi does deepan, pachan of aama present in body by clearing strotas and providing good channel for vayu.
 - Ashwagandha, bala and erandmoola are madhura, vrishya and provides strength to the body parts due to its property as vatahara.
 - Ghee and erand taila balances the rukshata by its snigdha guna with anulomana of vayu as additional property of erand taila.
 - Once the channel is free of aama with good vatanulomana the balya dravyas act on the vata locations providing strength to it.
 - As these dravyas act on pakwashay which is the main site of vata, vata is best balanced and strength is provided. Hence principle treatment is achieved Good here.
- The ingredients of rasnadi guggul are rasna, erandamoola, guduchi, deodara and shunthi. Acharya charak has mentioned tikta dravya ghrita and kshira in treatment of asthi dhatu

dushti. Rasnadi guggul has predominance of tikta rasa.

- Tikta rasa have properties like deepana, pachana and rochana. Thus, it helps to strengthen the joints along with the whole body.
- Tikta rasa also have daha prashamana property hence that may act as anti-inflammatory agent hence helps to reduce pain and swelling in the joints.
- Tikta rasa performs lekhana karma which helps in scrapping of sanchit meda thus helping in reduction of weight. If Katigatvat is due to obesity which is one of the factors, lekhana karma helps in relieving sandhigat vata.
- Kati is main site of vata which is also the site of shleshaka kapha. Tikta rasa helps in pacifying kapha dosha with proper nutrition to other dhatus. This may be the result of the drug on asthivaha strotas. Hence Principle treatment is achieved good here.
- Comparatively trial drug -Rasnadi kwath ghanvati showed more effect it may be due to combined effect of drugs along with anupan used. The study was conducted in 30-60 years age group and Ashwagandha and bala helps for dhatu Vardhan giving rasayana effect on all dhatus so better results were observed.

❖ CONCLUSION

In present study, from observation and results, it can be concluded that-

- Efficacy of Rasnadikwathghanvati (Trial group) and Rasnadi guggul (Control group) on subjective criteria & objective criteria has been statistically proved.
- Very few patients were having symptoms sparshasahatva and sandhi sputan. So efficacy of drugs can't be drawn in case of sparshasahatva and sandhi sputan.
- Both groups show mild to moderate reduction in symptoms of katigatavata.
- Efficacy of Rasnadikwathghanvati (Trial group) and Rasnadi guggul (Control group) has significant difference according to statistics.
- RasnadiKwathghanvati has more significant results in Katigatavata.

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